醫院管理局
HOSPITAL AUTHORITY

Name of Hospital: Hospital Authority Head Office Standing Quotation Ref: NPS24-005

Agreement No: _____ File Ref.: _____

Invitation to Quote
for the Supply of Surgical Stapler for Endoscopic Surgery under Nominated Product Scheme for Hospital Authority

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LODGING OF STANDING QUOTATION

Standing quotation is invited for the supply of Surgical Stapler for Endoscopic Surgery under Nominated Product Scheme for Hospital Authority. To be acceptable as a Standing Quotation, interested sellers must complete all Schedules as required **in duplicate in hard copy** with a soft copy in a compact disc and enclosed in sealed plain envelopes marked "Supply of Surgical Stapler for Endoscopic Surgery under Nominated Product Scheme (ref.: NPS24-005), Quotation Closing Date: 11 September 2024" and addressed to the Chairman, Tender Opening Committee, and deposited in the Hospital Authority Head Office Tender Box situated at 3/F., Lobby, Hospital Authority Building, 147B Argyle Street, Kowloon before **12:00 noon (Hong Kong Time) ("Closing Time") on 11 September 2024 ("Closing Date").**

INTERPRETATION

(a) In this Invitation to Quote, the following words and expressions shall have the following meanings, unless the context otherwise requires:

"Authority" or "HA"	means the Hospital Authority, a statutory body established under the Hospital Authority Ordinance, Cap. 113 of the Laws of Hong Kong to manage and control public hospitals in Hong Kong;
"Authority Representative"	means the Chief Executive acting for and on behalf of the Authority or any duly authorized officer for the time being performing his duties;
"Buyer"	means the Authority or a Hospital, as the case may be;
"Chief Executive"	means the Chief Executive of the Authority;

"Consignment Stock Scheme"	means an arrangement through which Goods are deposited by an approved Nominated Product Scheme Seller at a Hospital, for purchase and use by hospitals, on an "as and when required" basis;
"Contract"	means the Contract to be made for the supply of the Goods by the Seller to the Authority or Hospital on (i) the terms set out in this Invitation to Quote; (ii) to the extent agreed by the Authority, the terms set out in the Standing Quotation by the Seller; and (iii) any other terms agreed between the Authority and Seller;
"Goods"	means the Goods listed in the Standing Quotation set out in **Schedule A**;
"Hospital"	means a public hospital under the management of the Authority;
"Purchase Order"	means the individual purchase order placed by the Buyer for the supply of Goods against the Standing Quotation and negotiation (if any) consequent thereon;
"Nominated Product Scheme" or "NPS"	means a method of fast-track purchase without committed consumption established by the Authority. Through the Standing Quotation with selected Sellers, type-approved brands/models may be purchased by the Buyer without having to seek quotations on each occasion;
"Seller"	means as the context requires, a party: (a) who is submitting a Standing Quotation, or (b) whose Standing Quotation is accepted by the Authority;
"Standing Quotation"	means the offer by the Seller as set out in **Schedule A** indicating the Goods, their price(s), specifications and countries of origin;
"Standing Quotation Submission"	means the completed Standing Quotation (including the relevant Schedules) submitted by a Seller to the Authority; and
"Validity Period"	means the term of the Standing Quotation – a period of twenty-four (24) months commencing from the date as specified in the Authority's letter of acceptance of the Seller's Standing Quotation, subject to early termination as provided in the Contract.

(b) Definitions used in one part of this Invitation to Quote shall apply to other parts, unless otherwise stated.

(c) References to paragraphs, sub-paragraphs, clauses or sub-clauses are references to paragraphs, sub-paragraphs, clauses or sub-clauses of this Invitation to Quote unless otherwise specified.

(d) Headings are for ease of reference only and do not form part of this Invitation to Quote.

(e) References to Schedules are references to Schedules of this Invitation to Quote which are incorporated as part of this Invitation to Quote.

(f) References to an Ordinance, statutory provision or statutory instrument include a reference to that Ordinance, statutory provision or statutory instrument as amended, extended or re-enacted from time to time and to any regulations made under it.

(g) The masculine gender includes all other genders and vice versa. The singular includes the plural and vice versa.

(h) In this Invitation to Quote, where the Authority's "agreement", "acceptance", "discretion" or "consent" is required or where the Authority has any right or power under this Invitation to Quote or where it is entitled to form an opinion (including words to such effect), the Authority may do so in its absolute discretion.

(i) A reference to a specific time for the performance of an obligation is a reference to the time in Hong Kong unless otherwise stated.

(j) A reference to working days means Monday to Friday inclusive, excluding public holidays in Hong Kong.

PART I – TERMS OF STANDING QUOTATION

1. Invitation to Quote

Sellers are invited to submit a standing quotation for the supply of Surgical Stapler for Endoscopic Surgery to be delivered subject to and in accordance with the Terms of Standing Quotation (Part I), Quotation Subject Matter (Part II) and the Terms and Conditions (Part III). This Invitation to Quote, identified as NPS24-005, consist of:

(a) Part I – Terms of Standing Quotation
(b) Part II – Quotation Subject Matter
(c) Part III – Terms and Conditions ("T&Cs")
(d) Part IV – Schedules (A to H)
- Schedule A – Details of Offered Goods and Price
- Schedule B – Schedule of Compliance
- Schedule C – Instructions for Storage and Handling of the Goods
- Schedule D – Consumption Report
- Schedule E – On-Loan Instruments Provided to HA on Free of Charge Basis
- Schedule F – Details of the Safety Alert System and Product/Instrument Recall System
- Schedule G – Declaration of Conflict of Interest by Seller
- Schedule H – General Specifications

(e) Part V – Memorandum of Acceptance

All supplementary information to this Invitation to Quote will be in writing and forwarded by post, e-mail or fax to all sellers known to be in receipt of this Invitation to Quote. Sellers must acknowledge receipt of all such supplementary information. Sellers are also provided with the following documents for information:

Information Document (At the back of this Invitation to Quote)

(f) Notice for Submission of Standing Quotations
(g) Review Body on Bid Challenges

2. Standing Quotation

2.1 This Invitation to Quote relates to the Quotation Subject Matter. The Authority has the intention to establish a Nominated Product Scheme (NPS) for Supply of Surgical Stapler for Endoscopic Surgery in compliance with the requirements in this Invitation to Quote. The Authority has made a tentative plan to commence the NPS on 1 February 2025. The exact commencement date will be specified in the Authority's letter of acceptance of the Seller's Standing Quotation.

2.2 The Standing Quotation and all required information (if applicable) must be completed in English or Chinese (except where technical information is expressly required to be provided in English) and in permanent ink or typescript and submitted in the manner stipulated in this Invitation to Quote. Sellers are required to stamp and initial next to any corrections made. Where documents to be provided as part of the Standing Quotation Submission are in a language other than the English or Chinese language, a true, accurate and complete English or Chinese translation certified by the translator stating his/her relevant qualifications shall

be provided with the original foreign-language document. Standing Quotations not so completed may not be considered.

2.3 The Schedules issued with this Invitation to Quote must not be altered by the Sellers. Sellers must submit their Standing Quotations on the basis that they accept and agree to all terms and conditions in this Invitation to Quote.

2.4 TWO (2) sets of product information, e.g. catalogues, certificates, technical specifications, brochures, and so on, both hard copies and soft copies for the Goods offered, shall be submitted with the Standing Quotation. Additional copies may be requested by the Authority to facilitate easy reference and evaluation.

2.5 Standing Quotation Submission may not be considered if complete information is not given with the Standing Quotations or if any particulars and data asked for in the Schedules are not furnished in full. Where appropriate, descriptive and technical literature on the Goods shall be submitted with the Standing Quotations. The Authority may request clarification of particulars and data supplied, or additional particulars and data, and if so the Seller shall have five (5) working days or such further period as the Authority may specify to submit such further information. Failure to do so within the time period may deem the Standing Quotation Submission incomplete and such Standing Quotation Submission may not be considered.

2.6 Any enquiries from Sellers concerning this Invitation to Quote up to the date of lodging their Standing Quotation Submission with the Authority shall be in writing and shall be submitted to:

Attention : Ms Anna YAU, Supplies Officer (PMD)
Telephone : (852) 2300 7466
Fax : (852) 2515 9046
Address : Room 310N, 3/F, Hospital Authority Building,
147B Argyle Street, Kowloon, Hong Kong
E-mail Address : ysl218@ha.org.hk

2.7 Any complaints from Sellers about the quotation process or contract award must be in writing and shall be submitted to:-

Hospital Authority Head Office
Procurement & Materials Management Section
Attention : Senior Manager (Business Support Services)2
Address : Room 313N(A), 3/F, Hospital Authority Building,
147B Argyle Street, Kowloon, Hong Kong
E-mail Address : haho_bss_sm@ha.org.hk
Tel : (852) 2300 7433

2.8 Subject to Clause 2.10 below, after lodging a Standing Quotation Submission with the Authority, the Seller shall not attempt to initiate any further contact, whether direct or indirect, with the Authority on its Standing Quotation Submission. The Authority shall have the sole right to initiate any such further contact and any replies to the Seller thereto shall be in writing or formally documented in writing.

2.9 Complete information, including descriptive and technical literature, on the Standing Quotation Subject Matter must be submitted. The Seller is invited to supply any other information considered to be relevant to the evaluation of its Standing Quotation Submission.

2.10 Sellers must inform the Authority in writing immediately of any circumstance or information which may affect their qualifications to quote in the Standing Quotation Submission. The Authority reserves the right to review their qualified status in the light of any new information relevant to their qualification.

3. Standing Quotation Preparation

3.1 The Standing Quotation and all accompanying documents must be completed and submitted in the manner stipulated under 'Lodging of Standing Quotation' on the front page of this Invitation to Quote. If the Standing Quotation is to be submitted via a courier and a receipt is needed, the courier should be instructed to contact the Tender Opening Committee Registry at Room 310N, Hospital Authority Building, 3/F, 147B Argyle Street, Kowloon before the courier deposits the Standing Quotation into the Tender Box.

3.2 Late Standing Quotation Submission will not be accepted, except under very special circumstances, due to unforeseen circumstances e.g. act of God or a genuine mistake by a courier company (with proof of the Standing Quotation Submission being kept intact during transit before the closing date). The Authority shall have absolute discretion to accept late Standing Quotation Submission in circumstances which the Seller can demonstrate were beyond the Seller's control.

4. Standing Quotation Prices

4.1 Sellers are requested to quote the prices in Hong Kong dollars, which must be net prices allowing for all trade and cash discounts and inclusive of all cost and expense to be incurred by the Seller in the performance of the Contract.

4.2 Unless a Seller clearly stipulates otherwise in its Standing Quotation, the prices quoted in the Standing Quotation must remain valid for the Validity Period. Therefore no request for price increase will be considered. If however a Seller, for commercial reasons, wishes to adjust the prices downward for the remaining of the Validity Period or for a certain period of time during the Validity Period, it may do so. In any such case the basis of the price adjustment must be clearly stipulated and accepted by the Authority in writing. The revised Standing Quotation will then be used for placing Purchase Orders by the Authority or the Hospital. **No promotional offer to individual Hospital is allowed.**

5. Accuracy of Standing Quotation Prices

Sellers are reminded to ensure that the Standing Quotation prices quoted are accurate before submitting their Standing Quotations. Under no circumstances will the Authority accept any request for price adjustment on grounds that a mistake has been made in the prices quoted by a Seller.

6. Payment Discounts

Sellers are requested to indicate in the relevant section under **Schedule B** the discount they would allow on the Standing Quotation prices if payment for each Purchase Order is made in full within the specified period.

7. Standing Quotations to Remain Open

The Standing Quotation submitted by the Seller in response to this Invitation to Quote shall remain open for not less than 180 days after the Closing Date for the Authority's acceptance and the Seller shall not withdraw its offer within the 180 days.

8. Acceptance of Standing Quotations

8.1 The successful Seller(s) will receive notification by letter of acceptance of their Standing Quotations from the Authority. Sellers who do not receive any notification within 180 days after the Closing Date may assume that their Standing Quotation Submissions have not been accepted.

8.2 Seller(s) whose Standing Quotation(s) are accepted will be bound to supply Goods to the Authority/Hospitals pursuant to Purchase Orders placed by the Authority/Hospitals against their Standing Quotations or under the Consignment Stock Scheme as described in Part II (Quotation Subject Matter), on an "as and when required" basis, during the Validity Period and upon the terms and conditions of this Invitation to Quote. The Purchase Orders issued by the Authority/Hospital are subject to the terms and conditions of this Invitation to Quote.

8.3 Sellers should note that the Authority/Hospital is not bound to place orders against any Standing Quotations during the Validity Period and reserves the right to place orders against any part of their Standing Quotations as and when required during the Validity Period, or from other sellers.

9. Standing Quotation Evaluation Criteria

9.1 The Standing Quotations will be evaluated by an Assessment Panel set up by the Authority, in accordance with the requirement set out in Clause 2 of Part II.

9.2 Pursuant to Clause 9.1 above, in the event that any Seller or company has been excluded from participation in tendering by the Authority before the award of the Contract, the concerned Standing Quotation(s) will not be evaluated any further. The Authority may then consider and accept other conforming Standing Quotation(s) in accordance with the criteria for quotation evaluation stipulated in Clause 9.1 above giving any prior notice to the excluded Seller or company.

10. Life Expectancy of the Goods

Sellers shall submit the life expectancy, in terms of year, of the offered Goods in **Schedule A**.

11. Negotiation

The Authority reserves the right to negotiate with any Seller on the terms of the Standing Quotation Submissions.

12. Basis for Acceptance

Any Standing Quotation may be considered and accepted on an itemized basis. Sellers should note that the Authority reserves the right to accept Standing Quotations of more than one Seller.

13. Company Background and Financial Information

Seller shall provide the following details to the Authority with its Standing Quotation:

13.1 Name and address of the company / business organization.

13.2 Length and nature of business experience including without limitation experience in the performance and / or supply of the products as listed in **Schedule A**.

13.3 Shareholders / partners of the company / business organization.

13.4 Audited accounts/financial statements of the Seller for the past three years. The audited accounts/financial statements must include Director's report, Auditor's report, Profit and loss statement/Statement of comprehensive income, Balance sheet/Statement of financial position, Statement of cash flow and Notes to the Accounts/financial statements. The accounts/financial statements shall be prepared on the same basis for each year in accordance with accounting principles generally accepted in the Hong Kong Special Administrative Region and the disclosure requirements of the Companies Ordinance, Cap. 32/Cap. 622 of the laws of Hong Kong (as applicable), or for overseas company the equivalent requirements of the local government.

13.5 Projected profit and loss accounts/Statement of comprehensive income and cash flow statements for the Validity Period, showing the revenue, operating expenses, capital expenditure and the sources of finance such as upfront investment and/or debt financing.

13.6 A copy of its Articles of Association or other documents evidencing its business status.

13.7 Copies of the organization's Certificate of Incorporation with the companies registry (if incorporated), its current business registration certificate and its application form for registration of business.

13.8 Copies of all current licence(s) or permit(s) issued in favour of the Seller by the relevant authorities that are required to legally perform and / or supply the Goods (if applicable).

13.9 Documentary evidence of any agency claimed by the Seller in relation to the Goods listed in the Standing Quotation, whether on a sole or exclusive basis or otherwise.

14. Bona Fide Standing Quotation

Each Seller is required to sign a Certificate of Non-Collusion in the relevant section under **Schedule B** to certify that its Standing Quotation Submission is bona fide.

15. Quotation Closing Time in case of Rainstorm/Typhoon / "Extreme Conditions"

The Closing Time and Closing Date will be extended to 12:00 noon the next working day in Hong Kong (i.e. any day from Monday to Friday which is not a public holiday) under the following situations:

(i) a black rainstorm signal or tropical cyclone warning signal No. 8 or above or "Extreme Conditions" issued by the Government is still in force between 9:00 am and 12:00 noon on the Closing Date; or

(ii) it is announced by the Government between 9:00 am and 12:00 noon on the Closing Date that a black rainstorm signal or tropical cyclone warning signal No. 8 or above or "Extreme Conditions" will be issued in Hong Kong between 9:00 am and 12:00 noon on the Closing Date. For the avoidance of doubt, if it is announced by the Government that such signal will be issued at or before a time that falls beyond 12:00 noon on the Closing Date, there will not be any extension of the Closing Time or Closing Date unless the relevant signal is actually issued and is in force between 9:00 am and 12:00 noon on the Closing Date

16. Environmental Friendly Measure

16.1 The Authority is sensitive to the environmental impact of purchasing decisions and takes account of legitimate environmental concerns while continuing to achieve best value for money in its purchasing functions.

16.2 The following environment friendly measures are recommended in the preparation of the Standing Quotation:-

(a) All documents should preferably be printed on both sides and on recycled paper. Papers exceeding 80 gsm are not recommended as a general rule.

(b) Excessive use of plastic laminates, glossy covers or double covers should be avoided as far as possible. Use of recyclable non-glossy art board paper as document covers is recommended.

(c) Single line spacing should be used and excessive white space around the borders and in between the paragraphs should be avoided.

17. Seller Performance Monitoring

Sellers should note that in the event a Seller is awarded a contract by the Authority, the Seller's performance, including but not limited to product quality, after sales services and maintenance services, where applicable, in the contract shall be monitored and taken into account in evaluating the Seller's offers in response to invitations for quotes by the Authority. If, based on the Seller's performance record, the Authority has a reasonable concern about the Seller's legal and financial capabilities and

the commercial and technical abilities to undertake the relevant procurement, the Authority may in its absolute discretion (i) take into consideration the Seller's performance record, both for the equipment type(s) specified in the warning letter and for other equipment types/services provided by the Seller in the quotation evaluation and/or (ii) exclude that Seller, its holding company and subsidiaries from participation in tendering, for such period as the Authority may in its entire discretion consider appropriate. The Authority shall have the right to publicize or disclose, whenever it considers appropriate or upon request (verbal or written) by any third party, information of the Seller who has been excluded from participation in tendering by the Authority, such as the name of the Seller and duration, without reference to or consent from the Seller. Quotes from the Seller who has been excluded from participation in tendering by the Authority shall be rejected.

18. Code of Conduct

Having due regard to the Authority's corporate image and reputation and the Authority's need to uphold the same, the Sellers shall propose under the relevant section in **Schedule B** a code of conduct by reference to the "Sample Code of Conduct for Non-Governmental Organizations ("NGOs") / for Private Sector" issued by and obtainable from the Independent Commission Against Corruption ("ICAC"). The "Sample Code of Conduct for NGOs / for Private Sector" can be accessed via the link below in HA website under "Tender Notice":

http://www.ha.org.hk/visitor/ha_visitor_index.asp?Content_ID=2001&Lang=ENG&Dimension=100

19. Offering Gratuities

19.1 Seller shall not, and shall procure that their employees, agents and sub-contractors shall not, offer, solicit or accept an advantage as defined in the Prevention of Bribery Ordinance (Cap. 201 of the laws of Hong Kong) in connection with this Invitation to Quote.

19.2 Failure to so procure or any act of offering, soliciting or accepting advantage referred to in Clause 19.1 above committed by the Seller or by an employee, agent or sub-contractor of the Seller shall, without affecting the Seller's liability for such failure and act, result in its Standing Quotation Submission being invalidated.

20. Cancellation of Invitation to Quote

Without prejudice to the Authority's right to cancel the Invitation to Quote, where there are changes of requirements after the Closing Date, for operational or any other reasons, the Authority is not bound to accept any conforming Standing Quotation and reserves the right to cancel the Invitation to Quote.

21. Destruction of Unsuccessful Standing Quotations

Those unsuccessful Standing Quotation Submissions falling within the purview of the Agreement on Government Procurement of the World Trade Organisation ("WTO GPA") shall be destroyed 3 years after the date of the award of the Contract. Where this Invitation to Quote is cancelled (whether or not such Invitation to Quote is within the purview of WTO GPA), all Standing Quotations can be destroyed any time after cancellation.

22. Personal Data (Privacy) Ordinance

Sellers are requested to adhere to the requirements as stipulated in **Schedule B** in relation to the Personal Data (Privacy) Ordinance (Cap. 486 of the Laws of Hong Kong).

23. Conflict of Interest

23.1 Without limiting the Authority's right and the Seller's obligations under Clause 24 of Part III (Terms and Conditions), Sellers must declare in **Schedule G** whether any actual, apparent, potential or perceived conflict of interest will, or might, arise in the performance of their obligations under the Contract and the details of any such conflict. If at any time after submitting the Standing Quotation Submission and prior to entering into the Contract with the Authority, any actual, apparent, potential or perceived conflict of interest arises or may arise for or becomes known to any Seller which is inconsistent with the declaration in **Schedule G**, such Seller should immediately notify the Authority in writing.

23.2 The Authority reserves the right to reject any Standing Quotation Submission or take any other action it considers appropriate if, in the Authority's opinion, any conflict of interest will or might arise in respect of any Seller. However, identification of a potential or actual conflict of interest does not necessarily preclude a Standing Quotation Submission from consideration. The Authority will carefully consider the circumstances surrounding the conflict of interest to determine whether the Standing Quotation Submission should be rejected on this basis.

24. Minamata Convention on Mercury

The Sellers shall have intent to comply with the Minamata Convention on Mercury in the products on offer. Sellers shall provide confirmation of such intention in **Schedule B** in the Standing Quotation Submission. Full text of the Convention could be downloaded from the following URL:

https://www.mercuryconvention.org/en

25. The Sale of Goods (United Nations Convention) Ordinance (Cap. 641 of the laws of Hong Kong)

The provisions of the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Invitation to Quote and a Standing Quotation submitted by a Seller in response to this Invitation to Quote.

26. National Security

Notwithstanding anything to the contrary in this Invitation to Quote, the Authority reserves the right to disqualify a Seller on the grounds that the Seller has engaged, is engaging, or is reasonably believed to have engaged or be engaging in acts or activities that are likely to cause or constitute the occurrence of offences endangering national security or otherwise the exclusion is necessary in the interest of national security, or is necessary to protect the public interest of Hong Kong, public morals, public order or public safety. The Sellers shall in **Schedule B** confirm and warrant that they have not engaged, are not engaging and will not engage in the aforesaid acts or activities. Failure to

observe the requirement shall render all related submissions null and void and any such submission shall not be considered.

27. General

27.1 The Authority will not be responsible for or liable to any Seller for any cost or expense incurred in relation to (i) the preparation or submission of the Standing Quotation Submission; or (ii) any communication between the Seller and the Authority in relation to the Invitation to Quote, under any circumstances (including the cancellation of this Invitation to Quote by the Authority).

27.2 The Seller acknowledges and agrees that the Authority is not responsible for the accuracy of any information provided in this Invitation to Quote, and the Seller has made its own independent evaluation of the business potential of the Quotation Subject Matter and it has submitted its Standing Quotation Submission solely on the result of such independent evaluation.

PART II – QUOTATION SUBJECT MATTER

1. Background

1.1 The Authority is a statutory body incorporated in Hong Kong under the Hospital Authority Ordinance (Cap. 113 of the laws of Hong Kong). The objective of the Authority is to manage and develop Hong Kong's public hospital system to provide quality public health care services to the people of Hong Kong.

1.2 The Authority currently manages 43 public hospitals/institutions and over 123 outpatient clinics in Hong Kong. It provides over 30,000 hospital beds and about 21 million attendances of medical care per year through its outpatient clinics, day hospitals and community services.

1.3 The Authority wishes to engage multiple sellers to supply of Surgical Stapler for Endoscopic Surgery under the NPS for the Authority. Sellers should note that Goods under the NPS will be ordered by and supplied to either the Authority or any of the Hospitals during the Validity Period on an "as and when required" basis, and the Authority or a Hospital placing such Purchase Order shall be referred to as the Buyer.

2. Quotation Subject Matter

2.1 Sellers are invited for the supply of Surgical Stapler for Endoscopic Surgery under the NPS. Sellers must comply with the mandatory requirements and specification as stipulated in **Schedule H** for the supply of Surgical Stapler for Endoscopic Surgery. The product types and categories required by the Authority are set out in **Schedule A**. Sellers are invited to offer their Goods which rightly match with the required product types and categories, by completing all details and prices in **Schedule A,** the Schedule of Compliance in **Schedule B** and the requirements in **Schedule H**. Seller should note that any Goods quoted in Schedule A must have been consumed by HA/Hospital(s) (or equivalent in Hong Kong or elsewhere) within 18 months immediately preceding the Closing Date. Seller must complete the consumption details for each of the Goods it proposes to supply in **Schedule D**. The Authority shall have absolute discretion to determine what experience or consumption is "equivalent" in the circumstances.

2.2 Any Goods to be supplied by the Seller must meet the following product standards and requirements:

(a) the Goods offered must comply with the standard of British Standard Institution (BSI) of general requirements for Surgical Stapler for Endoscopic Surgery or equivalent standard of International Organization for Standardization (ISO). Sellers must indicate the specific BSI or ISO standard applicable to each offered products in **Schedule A, and** confirm compliance with the applicable standards. Upon request, Sellers are required to provide to the Authority documentary evidence showing compliance with the relevant standards;

(b) the Seller must, for each of the Goods quoted in **Schedule A**, submit with its Standing Quotation copies of 2 sets (each set in separate file) of the following:

(i) certified true copy of manufacturer license issued by the Government or Health Authority of the country of origin;

(ii) certified true copy of the authorized certification of compliance to ISO 13485 (latest version), Food and Drug Administration (FDA)/ Product's compliance with European Commission legislation (CE)//BSI or other equivalent international standards in production and quality-management system;

(iii) certified true copy of certifying compliance with FDA 510(K)/CE or other equivalent international standards for listing of each offered product in **Schedule A**.

2.3 If a Seller is not the manufacturer of the Goods offered in **Schedule A**, the Seller must submit with its Standing Quotation **a written undertaking** issued by the manufacturer of the Goods evidencing the manufacturer's agreement to supply such Goods to the Seller should the Seller's Standing Quotation be accepted by the Authority. The written undertaking shall be signed by a duly authorized representative of the manufacturer and dated no later than the Closing Date but not earlier than six (6) months before the Closing Date. If a Seller fails to submit the written undertaking on or before the Closing Date, or by the time specified by the Authority, its Standing Quotation may not be considered.

2.4 Sellers are to note that for each of the Goods under a Standing Quotation which has been accepted by the Authority, the Seller must, at the instruction of the Buyer, supply the Goods during the Validity Period either:

(a) as a stock item pursuant to a Purchase Order placed by the Buyer; or
(b) as a consignment item under the Consignment Stock Scheme.

2.5 The Buyer may at any time during the Validity Period, request the Seller to deposit certain quantities of any of the Goods which have been quoted in **Schedule A** at the Hospital premises as consignment stock under the Consignment Stock Scheme. The Buyer will notify the Seller when the Goods from the consignment stock are taken out for use, and will issue a Purchase Order to the Seller. The Seller may then invoice the Buyer as appropriate for the Goods consumed. The Seller must also top up from time to time during the Validity Period the quantity of Goods placed in consignment, in accordance with the quantities and time as required by the Buyer, and to replace any Goods in the consignment stock for which the expiry period has passed.

2.6 Sellers must complete and submit with their Standing Quotations **Schedule C** - instructions for storage and handling of the Goods under the Consignment Stock Scheme.

2.7 If during the Validity Period the Seller wishes to add new items to the list of Goods to be supplied under the NPS, the Seller must write to the Authority and propose the new items to be supplied, together with supporting written evidence that the said items have been consumed by HA/Hospital(s) (or equivalent in Hong Kong or elsewhere) in the past 12 months. The Authority shall have absolute discretion whether or not to add those proposed items onto the list of Goods in **Schedule A** but if it does, the supply of the new items shall be subject to the

terms of this Invitation to Quote. The Authority shall have absolute discretion to determine what experience or consumption is "equivalent" in the circumstances.

2.8 The Authority may at any time during the Validity Period, delete any items from any Standing Quotation either because (a) there has been no purchase record with the Buyer within the past 12 months; (b) bulk contract(s) has been established for such item; or (c) in the Authority's opinion, the items should no longer remain on the Standing Quotation. The Authority will inform the Seller of the items to be deleted and the effective date of such deletion.

2.9 As part of the Invitation to Quote exercise, the Seller is also invited to offer to the Authority in their Standing Quotations on-loan instruments (**"On-loan Instruments"**) for the Buyer's use with the Goods that Sellers quote in **Schedule A**. All On-loan Instruments offered must:

(a) be fully compatible with the Goods supplied by the Seller; and
(b) be provided to the Buyer free of charge.

The Seller is required to provide details of the On-loan Instruments (if any), including their selling prices, in **Schedule E**.

2.10 The Seller must have in place appropriate and adequate product safety alert system and product recall system covering the Goods (whether or not under the Consignment Stock Scheme) and the On-loan Instruments. The Seller must in **Schedule F**:

(a) describe the safety alert system in place in respect of the Goods and the On-loan Instruments;

(b) provide the details of the product recall system in place in respect of the Goods and the On-loan Instruments, which must have been approved by the relevant regulatory authority.

(c) The Seller must also provide the names, email addresses and telephone numbers of the representatives of the manufacturer and (in case the Seller is a local distributor) the Seller with whom the Authority can contact in the event of Safety Alert Notice or Product Recall Notice (both as defined in Clause 9 of Part III).

2.11 The Authority shall have the right to disclose whenever it considers appropriate, or upon request (verbal or written) by any third party (including unsuccessful Sellers) information on the Contract, such as the name and address of the successful Seller, product description/brand/model/country of origin (if applicable), description of the relevant services (if applicable) and the value of the Contract, without reference to or consent from the successful Seller. Unsuccessful Sellers may also enquire as to the reason for the rejection of their Standing Quotation Submissions.

3. Term of the Standing Quotation

Any Standing Quotation, once accepted by the Authority, will be valid through the Validity Period for the Buyer to order at the prices quoted in the Standing Quotation.

4. Estimated Quantities

The Authority and the Hospitals do not have commitment to order a minimum quantity of any items set out in **Schedule A** from any Seller(s) during the Validity Period.

5. Operational Training

The Seller is required to provide operational training to operators/users free of charge during the Validity Period. The operational training shall be designed to enable the operators/users to use the Goods safely, effectively and properly in all aspects. The Seller shall specify in the relevant section under **Schedule B** the type of operational training to be provided.

6. Ordinance Concerning Product Safety

6.1 Sellers shall quote in **Schedule B** the details of the licences and/or test certificate/report which are required for the provision of the offered product under the Ordinance of Hong Kong, e.g. Telecommunications Ordinance (Cap. 106 of the laws of Hong Kong), Factories and Industrial Undertakings (Lifting Appliances and Lifting Gear) Regulations (Cap. 59 of the laws of Hong Kong), etc.

6.2 If the Authority is required by law to maintain the licences or test certificates for the possession or use of the offered product, Sellers shall inform the Authority of such requirements in **Schedule B**.

7. Listing under the Medical Device Administrative Control System

7.1 Currently, there is no specific legislation that regulates the manufacture, import, distribution and sale of MDs (which may include medical equipment and consumables) in Hong Kong. In order to pave the way for implementing the long-term statutory control of medical devices, the Department of Health ("DH") of the HKSAR Government has set up the MDACS with the following features:

(a) a listing system for applicable MDs*, under which manufacturers of the applicable MDs or their respective local representative could voluntarily list their applicable MDs with DH; and

(* "Applicable MDs" are the Class II/III/IV general medical devices and Class B/C/D in-vitro diagnostic MDs according to the classification rules of MDs under MDACS.)

(b) an adverse event reporting system, through which the manufacturers (or their respective local representative), users, and the general public could report adverse events associated with medical devices to DH.

7.2 The MDACS is run by the Medical Device Division ("MDD") under DH. Sellers may visit MDD's website:

http://www.mdd.gov.hk/en/mdacs/index.html

or contact MDD at telephone number 3107 8484 or facsimile number 3157 1286 or via e-mail: mdd@dh.gov.hk for further information on the MDACS.

7.3 The Authority supports the MDACS's objective to safeguard patient safety, and has included in this Invitation to Quote the requirement for Sellers to commit the submission of their offered products which are applicable MDs to the MDD for listing under the MDACS by a date not later than six months after the contract commencement. Please provide relevant details on the listing in the **Schedule B** with supporting documents for all offered products which are applicable MDs. If Sellers' offered products (or any of them) are not applicable MDs according to the classification rules of MDs under MDACS or are otherwise not subject to listing under the MDACS, please declare the same and provide the relevant details in **Schedule B** with supporting documents.

7.4 The successful Sellers shall, upon request by the Authority, update the Authority the listing record of their offered products which are applicable MDs under MDACS and/or status of its submissions to DH for listing of such products under MDACS. If, in the sole opinion of the Authority, the successful Seller fails to submit its application(s) to DH before the committed date provided in accordance with **Clause 7.3 above** or the MDACS listing cannot be completed within twelve (12) months after contract commencement or the successful Seller's declaration under **Clause 3 in Schedule B** are found to be invalid, incorrect or unsubstantiated, the Authority may, without prejudice to the Authority's other rights and remedies under the contract or by law, exercise all or any of its rights under Clause 27.1 of Part III (Terms and Conditions) [and/or disqualify that Seller, its holding company and subsidiaries from participation in any future tenders issued by the Authority], as the Authority may in its absolute discretion consider appropriate.

7.5 Sellers shall confirm their agreement to comply with all statutory requirements within the prescribed period under the legislation should the statutory control of medical devices takes effect in **Schedule B**.

8. Electronic Data Interchange (EDI) Requirements

When required by HA, the Seller is required to install and use the GS1 Hong Kong's (a new name of Hong Kong Article Numbering Association) Web-based EZ*TRADE or the Gateway Solution to receive the Purchase Orders, send Purchase Order acknowledgements and other information on Vendor Managed Inventory (VMI) electronically with the Authority's Enterprise Resources Planning System (ERPS) (the "**EDI Requirements**") at its own cost. Details of GS1 Hong Kong's web-based EZ*TRADE and the Gateway Solution, and an implementation checklist are listed in Appendix I to Part II. The Seller is required to confirm compliance with the EDI Requirements in the relevant section under **Schedule B**.

9. Cataloguing and Data Cleansing Requirements

The Seller shall provide technical support to the Authority in development of item catalogues and data cleansing of the offered products in accordance with the Authority's policy and procedures ("**Cataloguing and Data Cleansing Requirements**"). The Seller is required to confirm compliance with the Cataloguing and Data Cleansing Requirements in the relevant section under **Schedule B**.

10. Order Records Requirements

The Seller is required to maintain an updated report on the purchase order history in respect of the Goods purchased by the Authority/Hospitals. Upon request of the Authority and unless otherwise specified, the Seller shall provide such report to the Authority within 7 working days. The report shall include details such as order number, date, hospital name, ordering quantity and value, batch no. and model no. of product delivered, etc. in the format as shown in **Schedule D**. The Seller is required to confirm compliance with the requirement under this Clause (the "**Order Records Requirement**") in the relevant section under **Schedule B**.

Appendix I to Part II

Electronic Data Interchange (EDI) Requirement

The Seller shall install and use the GS1 Hong Kong's (a new name of Hong Kong Article Numbering Association) Web-based EZ*TRADE or the Gateway Solution to receive the HA Purchase Orders, send Purchase Order Acknowledgements and other information on Vendor Managed Inventory (VMI) electronically with the Hospital Authority's Enterprise Resources Planning System (ERPS). All the fees mentioned below are for reference only. Sellers are required to check the updated information from time to time published by GS1.

Details of GS1 Hong Kong's Web-based EZ*TRADE and the Gateway Solution are as follows:-

The Web-based EZ*TRADE enables contractors to conduct EDI transactions by using a web browser on the Internet without involving additional set-up costs or special technical skills. The Gateway Solution, which requires communications software, internal IT support, an alignment of underlying processes and is for products which required Vendor Managed Inventory (VMI) with sophisticated transaction details. Implementation checklist for GS1 Hong Kong's Web-based EZ*TRADE and the Gateway Solution:

1. Join GS1 Hong Kong as member

Membership Fee : HK$3,440.00 for Entrance Fee (one off charge); and
HK$3,440.00 for Annual Fee

GS1 HONG KONG will assign mailbox ID, user ID and password to member for using Web EZ*TRADE Service.

2. Internal IT Consideration and System Installation Preparation

- Based on the tender requirement to determine the required solution to be implemented.
- Details please consult GS1 Hong Kong.

3. Inform Hospital Authority about the readiness of the system

4. Conduct testing with Hospital Authority

5. Align with Hospital Authority to agree on the Start Date

6. Monthly Charges to be paid (Please contact GS1 HK for payment procedure and updated monthly charges)

	Documents per month	Monthly Charges
Level 1 End Users	0 – 10	HK$50.00
Level 2 End Users	11 – 50	HK$100.00
Level 3 End Users	51 – 300	HK$200.00
	301 or above	HK$0.80/doc

PART III – TERMS AND CONDITIONS

1. Terms of Supply

1.1 Under the NPS, the Seller shall supply the Goods at the instructions of the Buyer during the Validity Period, upon and subject to these Terms and Conditions ("T&Cs"):

(a) as stock item in accordance with a Purchase Order to be issued by the Buyer from time to time against the Standing Quotation accepted by the Authority; or

(b) as consignment item under the Consignment Stock Scheme.

1.2 The Buyer however, is not bound to purchase any Goods during the Validity Period. The Buyer reserves the right to place orders from more than one seller under the NPS or from other non-NPS sellers.

2. Delivery and Default

2.1 Prior to delivery to the Buyer, the Seller shall check and ensure that all Goods are properly packaged, packed, marked, labelled and stored in accordance with the specifications or recommendations of the manufacturer.

2.2 The Goods shall be delivered by the Seller in accordance with the specific requirements as set out in the Purchase Order, such as the type and quantity of the Goods, the location and time of delivery. Each delivery shall be accompanied by a copy of the corresponding Purchase Order. The Seller shall ensure that it obtains a receipt from the Buyer when the Goods are delivered, but such receipt shall not constitute an acknowledgement that the Goods therein mentioned are acceptable or satisfactory to the Buyer.

2.3 The Buyer may change any delivery schedule by prior notice to the Seller (whether in relation to the place or the time of delivery of all or part of the Goods covered by such Purchase Order). The Buyer may cancel any Purchase Order wholly or in part by notice to the Seller at any time after the issue of Purchase Order but before delivery of the Goods.

2.4 Following the receipt of a Purchase Order issued by the Buyer, if the Goods are not delivered within the required delivery time, the Buyer may, without prejudice to any other rights which the Buyer may have against the Seller, terminate the Purchase Order, or reject the Goods (in whole or in part) and return them to the Seller at the own risk and expense of the Seller, and/or recover from the Seller any costs incurred by the Buyer in obtaining substitute Goods from a third party.

3. Title and Risk

Except for Goods under the Consignment Stock Scheme, and subject to the Buyer's right to reject and the consequences thereof, title to and risk in the Goods shall pass to the Buyer on issue of the receipt under sub-clause 2.2 of these T&Cs above. The Buyer will not be responsible for any Goods delivered but not contained in the Purchase Order.

4. Inspection, Testing, Acceptance and Rejection

4.1 The Seller shall provide, on request by the Buyer, tests in respect of the Goods to ensure compliance with their specifications. If so required, the Seller shall at its own cost furnish the Buyer a proof note or a certificate satisfactory to the Buyer to that effect.

4.2 All Goods delivered may be subject to inspection and/or testing by the Buyer and shall be deemed to have been accepted only when:

(a) the Authority Representative or any person duly authorized by him, furnishes the Seller with an acceptance note; or

(b) a period of 30 working days from the date of delivery has expired and the Goods have not been rejected by the Buyer,

whichever date is the earlier. The time taken on the part of the Buyer in inspecting or testing the Goods shall not prejudice the Buyer's right to reject the Goods or terminate the Purchase Order in whole or in part.

4.3 If the Buyer becomes aware of any shortfall in the Goods delivered, it shall notify the Seller. Upon being so notified, the Seller shall at the Buyer's option either:

(a) make an immediate additional delivery to make up the deficiency; or

(b) issue a credit note for the shortfall.

4.4 The Buyer may reject any Goods delivered which are not in accordance with the Contract or which in the Buyer's reasonable opinion do not conform with their specifications or which are defective or damaged, or not of merchantable quality or fit for the purpose for which they are reasonably intended or required.

4.5 Upon receipt of notice from the Buyer of the rejection of any Goods, the Seller shall at its own cost remove the same within 48 hours or the time frame specified by the Buyer. If the Seller fails to remove any rejected Goods within such period, the Buyer may dispose of the Goods as it sees fit and no liability shall attach in respect of such disposal. The Seller acknowledges and accepts that the Buyer bears no responsibility whatsoever for the custody of the rejected Goods from the time they are delivered to the Buyer to the time they are removed or disposed of.

4.6 Without prejudice to the Buyer's other rights and remedies, statutory or otherwise, in the event of rejection the Buyer shall be entitled to one or more of the following remedies:

(a) to require the Seller to supply replacement Goods;

(b) to require the Seller to refund the price or any part of the price which has already been paid for the rejected Goods; and/or

(c) obtain alternative supplies (whether equivalent or otherwise) from any other supplier and recover from the Seller any costs incurred in obtaining substitute Goods.

4.7 Acceptance of any partial delivery of Goods under any Purchase Order shall not bind the Buyer to accept any further delivery not conforming to the Buyer's requirements.

5. Consignment Stock Scheme

5.1 The Sellers shall, at the request of and within the time required by the Buyer, deposit such quantities of Goods at the designated Hospital premises as consignment stock under the Consignment Stock Scheme for use by the Buyer on an "as and when required basis". The Seller will be notified (without affecting or otherwise relieving the responsibilities of the Seller as set out in sub-clauses 5.3 and 5.5 of these T&Cs below) when the Goods are taken out from the consignment stock for use by the Buyer.

5.2 Title and risk of all Goods deposited and stored at the Hospital premises under the Consignment Stock Scheme shall remain with the Seller until the Goods are taken out from the consignment stock for use by the Buyer. Neither the Authority, nor any Hospital where consignment stock is stored, shall be liable for any loss of or damage to the Goods when they are deposited and stored at Hospital premises, whether or not due to any act or omission of the Authority, its staff or employees.

5.3 The Seller shall be solely responsible for carrying out all appropriate inspections and checking of the Goods which are deposited and stored at Hospital premises from time to time under the Consignment Stock Scheme, so as to assure that the Goods are in good condition and to be replaced if they are expired, and stock take the Goods for audit and replenishment purposes.

5.4 The Buyer's sole responsibilities to the Seller in connection with the Goods deposited under the Consignment Stock Scheme shall be to:

(a) permit the placement of the Goods at the Hospital premises;
(b) take reasonable care to prevent tampering with, or theft of, the Goods;
(c) store and handle the Goods in accordance with any instructions provided by the Seller as set out in **Schedule C**; and
(d) provide reasonable assistance to the Seller to conduct stock taking and inspection at Hospital premises;

Apart from the foregoing, the Buyer shall have no other responsibilities to the Seller whatsoever.

5.5 The Seller shall conduct regular checks on the stock under the Consignment Stock Scheme from time to time during the Validity Period and (a) top up the quantities of the Goods to the level as required by the Buyer; and (b) replace the Goods which have passed their expiry dates.

5.6 The Seller shall also be responsible to keep track of the products in the consignment stock in respect of:

(a) traceability of the products (e.g. batch/lot number);
(b) product expiry date, if applicable;
(c) replacement of expired products; and
(d) product alert/recall.

6. Quality and Description

6.1 The Seller represents and warrants that the Goods:

(a) will be of merchantable quality and fit for the purpose for which they are reasonably intended or required;

(b) will be free from defects in design, material and workmanship;

(c) shall be in conformity with the quantity, descriptions and other requirements stated in the Buyer's Purchase Order and will correspond with their published specifications in all respects;

(d) where applicable, conform in all respect with any samples provided by the Seller;

(e) will, in relation to the manufacture thereof, comply with all enactments, orders, regulations or other instruments issued by the government or other competent authority in their place of manufacture;

(f) will only be manufactured in the place of origin specified in the Seller's Standing Quotation or otherwise expressly agreed in writing by the Buyer;

(g) will comply with all applicable laws, regulations, statutory requirements and requirements of any competent authority (including those relating to health, safety, importation, registration, sale and use) in both the country of origin and in Hong Kong;

(h) (other than consignment stock) shall have an expiry date of not less than 18 months from the date of delivery to the Buyer, or such other period as agreed by the Buyer; and

(i) in respect of consignment stock, shall have an expiry date of not less than 18 months from the date of deposit at Hospital premises, or such other period as agreed by the Buyer.

6.2 All manufacturers' quality assurance/control report of the product(s) must be properly filed and submitted to the Buyer upon request.

6.3 The Seller acknowledges that the Goods are intended to be distributed to the public hospitals for use by, administration on, consumption, possession by and supply to patients of the public hospitals. The Seller shall be fully responsible for and shall indemnify the Buyer against any claim made by anyone in respect of the Goods resulting directly or indirectly from or in connection with the failure by the Seller to comply with any term of the Contract and/or the Purchase Order.

6.4 The Seller must keep the Buyer advised of any changes in Goods including but not limited to change in design, material, part numbers, supersessions, during the Validity Period.

6.5 The Seller shall undertake to provide the Authority at any time before Goods delivery with an option to substitute Goods with new technology for any or all of the offered Goods. The substitute Goods shall have performance characteristics and functional capability equivalent to or better than the originally offered Goods. Such substitution(s) shall cost less than or equal to the replaced Goods. These Terms and Conditions shall remain applicable to such substitutions(s) and the Authority reserves the right to accept or reject the proposed substitution(s).

6.6 Where product labelling and/or shelf life requirements are set out in the specifications, the use before date of all medical devices and consumables, if indicated in the format of MM/YY, will be made reference as use before the first day of the month.

7. Warranty and Guarantee

7.1 Without prejudice to the generality of Clause 6 of these T&Cs, the Seller will provide a warranty of and guarantee the quality of the Goods, and any part or portion thereof, for a period of 12 months from the date of acceptance thereof. In respect of Goods supplied under the Consignment Stock Scheme, the warranty and guarantee period shall be 12 months from the date they are taken out from the consignment stock for use by the Buyer.

7.2 Notwithstanding Clause 4 of these T&Cs, the Seller shall make good as soon as possible and without charge, all defects in the Goods arising from defective design, materials, workmanship or any other cause discovered within the said period referred to in sub-clause 7.1 of these T&Cs above.

7.3 In the event that the Seller is required to replace any defective Goods but it does not at the same time call for the return of the defective Goods, no responsibility for the defective Goods shall rest upon the Buyer, and the Buyer may dispose of them after a reasonable time in whatever manner as it sees fit and retain any proceeds, if any, thereof.

7.4 If any defects are not made good within a reasonable time, the Buyer may, after serving notice of intent on the Seller, proceed to rectify the defects by repair or replacement at the Seller's risk and expense without prejudice to any other rights which the Buyer may have against the Seller.

7.5 The Seller shall remain liable to the Authority under the terms of this clause whether or not the Goods, or any part thereof, were manufactured by it, and the Seller shall ensure that the supplier of any Goods not manufactured by it shall be under at least the same liability to the Seller as the liability undertaken by the Seller to the Buyer pursuant to this clause.

8. On-loan Instruments

8.1 The On-loan Instruments to be provided by the Seller to the Buyer during the Validity Period must be compatible for use with the Goods, and shall be provided for the Buyer's use free of charge. The Seller shall be responsible for the cost of delivery to and collection from the specified locations.

8.2 Title and risk of the On-loan Instruments shall remain with the Seller who shall be responsible for the proper maintenance of the instruments, including but not limited to reasonable periodic preventive and corrective maintenance, to ensure their safety standard is maintained at all times and that they are fit for the intended use.

8.3 The On-loan Instruments must comply with all applicable laws, regulations, statutory requirements and requirements of any competent authority (including those relating to health, safety, importation, registration, sale and use) in both the country of origin and in Hong Kong.

8.4 The use of the On-loan Instruments must not infringe any patent or copyright or third party intellectual property rights.

8.5 The Seller must provide all relevant documentation (including but not limited to operating manuals) to the Buyer and must provide necessary training to the Buyer to ensure Buyer's safe and proper operation of the On-loan Instruments.

8.6 The Seller shall not claim for damages to any of the On-loan Instruments that are caused by wear and tear under normal use by the Buyer. If the On-loan Instruments are lost or destroyed whilst in the custody of the Buyer, the Seller and the Buyer shall agree on a fair value thereof to be paid for such instruments but such amount, if any, shall not exceed the selling prices of the instruments as provided by the Seller in **Schedule E**.

9. Product/Instrument Safety Alert and Product/Instrument Recall

9.1 If the Goods/On-loan Instruments do not meet the criteria in Clause 6 or Clause 8 of these T&Cs, or if there is local or overseas adverse incident, e.g. product recall, hazard alert, etc., the Seller is obligated to inform the Authority in writing via e-mail (haho_bss_qa@ha.org.hk) within 24 hours after the Seller has known or reasonably should have known the happening of the incident, giving full details of the incident and its proposed response.

9.2 The Seller's product safety alert notice ("**Safety Alert Notice**") must be issued even if the Seller disputes legal liability for the problem or the hazard, or requires more time to establish remedial actions to be undertaken in relation to it, and the Safety Alert Notice shall not relieve the Seller from any other liability or obligation under the Contract and/or the Purchase Orders. The Safety Alert Notice must contain at least the following information:

(a) the manufacturer and the type/brand/model of the Goods/On-loan Instruments in question;
(b) the safety issue in question;
(c) when and how the safety issue was discovered;
(d) the distribution list of affected type/brand/model of the Goods/On-loan Instruments delivered to the Buyer;
(e) the manufacturer's recommendation in respect of the patients who may have used the Goods/On-loan Instruments in question and other action that needs to be taken.

9.3 The Seller's product recall notice ("**Product Recall Notice**") must contain at least the following information:

(a) the manufacturer and the type/brand/model of the Goods/On-loan Instruments in question;
(b) the safety issue in question;
(c) when and how the safety issue was discovered;
(d) the distribution list of affected type/brand/model of the Goods/On-loan Instruments delivered to the Buyer;
(e) the anticipated duration of the product recall exercise;
(f) whether the product recall is at hospital level or on patient level;
(g) the manufacturer's recommendation in respect of patients who may have used the type/brand/model of the Goods/On-loan Instruments in question and other action that needs to be taken;
(h) whether the Department of Health has been alerted.

9.4 The Seller's Safety Alert Notice or the Product Recall Notice (as the case may be) must comply with regulatory requirements (including as to registration requirements) and align with industry practice of goods similar to the Goods and/or the On-loan Instruments. The Seller must inform the Authority timely as and when new information emerges in respect of the Safety Alert Notice or the Product Recall Notice, in particular, with respect to safety issues or management of patients' clinical condition.

9.5 After receipt of a Safety Alert Notice, the Authority may, without prejudice to other rights and remedies of the Authority under the Contract and/or the Purchase Order or at law, reject the Goods (or any part thereof) delivered or return the On-loan Instruments, and may:

(a) suspend the performance of the Contract and/or the Purchase Order or any other contract (including cessation of any use or distribution of the Goods) until the safety issue is addressed to the satisfaction of the Authority; or
(b) terminate the Contract and/or the Purchase Order whereupon Clause 19 of these T&Cs shall apply.

9.6 (a) After receipt of a Product Recall Notice, without prejudice to other rights and remedies of the Authority under the Contract or at law:

(i) the Seller must, on demand by the Authority, repay to the Authority the price of the Goods subject to a Product Recall Notice (**"Recalled Goods"**); and/or
(ii) the Authority may accept products offered by the Seller to replace the Recalled Goods; and/or
(iii) the Authority may purchase from other sources alternate supplies to substitute for the Recalled Goods and the Seller must, on demand by the Authority, pay to the Authority any price difference above the price of the Recalled Goods and all the related freight and delivery charges.

(b) Additionally, the Authority may:

(i) suspend the performance of the Contract and/or the Purchase Order and/or any other contract (including cessation of any use or distribution of the Goods) until the problem underlying the Product Recall Notice is rectified; or
(ii) terminate the Contract and/or the Purchase Order and/or any other contract, whereupon Clause 19 of these T&Cs shall apply.

9.7 Where the Authority suspends the performance of this Contract and/or the Purchase Order pursuant to sub-clause 9.5 or sub-clause 9.6 of these T&Cs, or the Seller suspends supply of the Goods under this Contract and/or the Purchase Order, the Authority may purchase from other sources alternate supplies to cover Goods which the Authority may further order and the Authority shall be entitled to recover the cost of the such alternative supplies from the Seller.

9.8 Where, as a result of a Safety Alert Notice or a Product Recall Notice, the Authority has to:

(a) require its staff to work overtime in getting together the Goods and/or On-loan Instruments, which are subject to the Safety Alert Notice, or the Recalled Goods, maintaining the continuity of supplies (such as sourcing alternate supplies), stock-taking its inventory, compiling a list of patients who may be affected and contacting them, and providing follow up consultations and treatment that may be required, and has thereby incurred staff overtime cost (**"Staff Overtime Cost"**); and/or

(b) provide the affected patients with such medication (including alternate supplies) and such medical examination (including tests, radiological examinations) as may be necessary, and has thereby incurred expenses (**"Additional Expense"**); and/or

(c) incur other expenses (**"Other Expense"**);

the Seller must on demand by the Authority pay to the Authority the Staff Overtime Cost, the Additional Expense, and the Other Expense.

9.9 The Seller shall indemnify and keep indemnified the Authority in full against:

(a) any loss, damages, liability, cost and expense of any nature (including legal expenses) which may be incurred or suffered by the Authority; and

(b) any demand, claim and action against the Authority

arising out of or in connection with a Safety Alert Notice, a Product Recall Notice or the suspension in the supply of the Goods under the Contract and/or Purchase Order.

9.10 For the avoidance of doubt, the Authority may act in accordance with Clauses 9.5, 9.6, 9.7 and 9.8 of these T&Cs without incurring any liability to the Seller even if the Goods, which are subject to the Safety Alert Notice, and/or the Recalled Goods are later confirmed by any laboratory analysis, health or regulatory authority or by a court of law (whether or not in Hong Kong) to have complied fully with the relevant provisions of these T&Cs.

9.11 Notwithstanding anything herein, the Seller shall remove all Goods on consignment at Hospitals which are subject of a Safety Alert Notice or a Product Recall Notice within 48 hours of the issuance of such notice and, to the extent practicable, replace them with alternative Goods.

10. Additional Warranties

10.1 The Seller represents and warrants to the Buyer that:

(a) the Seller has all necessary title to the Goods and full right and authority to transfer title of the Goods to the Buyer;

(b) the possession, administration, use, distribution or supply of the Goods by the Buyer on or to its patients shall not infringe any third party proprietary rights, including any intellectual property rights (meaning any patents, trade marks, service marks, copyright, design rights, confidential information and other intellectual property rights (whether or not registerable) in Hong Kong or elsewhere including applications for the grant of such rights) (**"Intellectual Property Rights"**);

(c) the Goods shall be delivered free from any security interest or other lien or encumbrance;

(d) it has taken out and shall maintain adequate insurance with a reputable insurer to cover all liabilities in respect of personal injury or death of any person (including without limitation, the Seller's or (if applicable) sub-contractor's staff and visitors) and loss or damage to property (real or personal) under ordinances, statute or common law arising out of or in connection with the Seller's performance of or failure to comply with the provisions of the Contract (whether by itself, its agent or sub-contractor, if any).

11. Indemnity

11.1 The Seller shall indemnify the Buyer, its officers, employees and agents on demand in full against all liability, loss, damages, costs and expenses (including legal expenses) threatened, claimed or awarded against or incurred or paid by the Seller (or its officers, employees or agents) as a result of, or in connection with:

(a) breach of any warranty given by the Seller;

(b) any claim of loss or damage (including death or personal injury) suffered by any person in respect of or from the storage, handling or use of the Goods/On-loan Instruments;

(c) any breach by the Seller of the terms of the Contract;

(d) any act or omission of the Seller or its employees, agents or sub-contractors (if any); and

(e) any damage to Buyer's property that may be caused including without limitation any interference caused.

11.2 For the avoidance of doubt, the benefit of all indemnities shall be extended to any committee established by the Buyer, the chairman or any member of the Buyer or of its committee, any public hospitals or any of its employee, officer and agents. The Authority shall hold the benefit of such indemnities on trust for such persons to the extent necessary to give effect to this provision.

12. Intellectual Property Rights

12.1 The Seller represents and warrants to the Buyer that:

(a) the Goods and/or the On-loan Instruments supplied by the Seller to the Buyer do not infringe any Intellectual Property Rights of a third party (whether in Hong Kong or elsewhere);
(b) where appropriate, the Seller has procured or ascertained and confirmed the current and valid registration of any Intellectual Property Rights in respect of the Goods and On-loan Instruments provided; and
(c) the possession, administration, use, distribution or supply of the Goods and/or the On-loan Instruments by the Buyer do not infringe any rights, including Intellectual Property Rights, of a third party.

12.2 The Seller shall at its own cost, and without prejudice to its representations and warranties, upon the Buyer's request and within the time stipulated, provide the Buyer with such information or documentation (including third party opinions) as the Buyer may require to assess the Intellectual Property Rights position of the Goods and/or the On-loan Instruments at any time during the Validity Period, and whether or not any allegation or claim in respect of their validity or infringement of third party rights has been made or threatened.

12.3 Without prejudice to Clause 11 of these T&Cs, the Seller shall indemnify the Buyer against any liability, loss, costs, claims, damages and expenses of any nature (including legal expenses) which may be incurred or suffered by the Buyer as a result of any misrepresentation or breach by the Seller of any representation or warranty in this Clause 12.

12.4 If at any time any allegation or claim of invalidity or infringement is made in respect of the Goods and/or On-loan Instruments against the Seller or the manufacturer of the Goods and/or On-loan Instruments, (whether in respect of third party Intellectual Property Rights or otherwise and whether made in the jurisdiction where the Goods/On-loan Instruments are manufactured, sold or anywhere in the world), or in the Seller's reasonable opinion is likely to be made, the Seller shall forthwith notify the Buyer. The Seller shall thereafter promptly inform the Buyer of all developments in connection therewith. Subject to all the arrangements being agreed with the Buyer and provided that:

(a) the specifications shall be fully met; and
(b) there shall be no delay or disruption with the administration of treatment to the Buyer's patients,

the Seller may at its own expense replace the Goods/On-loan Instruments concerned. All costs and expenses including delivery, removal, and recall of products, administrative and labour costs, overtime charges, incidental to or occasioned by the replacement (including those of the Buyer) shall be borne solely by the Seller.

12.5 If a claim is made by a third party against the Buyer in connection with the infringement of Intellectual Property Rights in respect of any Goods or On-loan Instruments, or of a nature which, if substantiated, would give rise to such a claim, the Buyer will:

(a) give the Seller notice in writing of any such claim being made or action threatened or brought against the Buyer;

(b) subject to the Seller providing such security against costs and damages as the Buyer may require, permit the Seller at the Seller's expense to conduct any litigation which may ensue and all negotiations for a settlement of the claim; and
(c) give the Seller all reasonable assistance, subject to reimbursement from the Seller of its reasonable costs.

The costs incurred or recovered by the Seller in such negotiations and litigation will be for the Seller's account.

12.6 The Buyer may also, at its election, without prejudice to other rights and remedies of the Buyer:

(a) forthwith terminate the Contract and/or Purchase Orders in respect of Goods not yet received by the Buyer;
(b) suspend the performance of the Contract and/or Purchase Orders until the claim in question is resolved to the satisfaction of the Buyer without prejudice to the Buyer's right to terminate such Contract and/or Purchase Orders any time after such election;
(c) obtain alternative supplies (whether equivalent or otherwise) from any third party suppliers; and/or
(d) without relieving the Seller's liability under this Clause 12, require the manufacturer of the Goods to enter into an intellectual property warranty and indemnity in favour of the Buyer substantially in the form of this Clause 12 (with the manufacturer being substituted for the Seller) as a pre-condition and requirement for the Buyer not to terminate the Contract and/or Purchase Orders, or otherwise cease to continue to purchase the Goods from the Seller.

12.7 The Buyer shall not be liable to the Seller for any loss, cost or expense incurred by the Seller or any third party arising from, or as a result of, the exercise by the Buyer of any right or remedy available to it under Clause 12 of these T&Cs, whether or not the allegation or claim in relation to which such right or remedy is exercised is later found by a court of law to have been validly made. The Seller irrevocably and unconditionally waives any right to make any claim for compensation arising therefrom, and to the extent the Buyer has any liability arising from its exercise of such rights and remedies hereby releases and discharges the Buyer from the same.

13. Buyer's Liability

13.1 The Buyer shall not be liable for or in respect of any damages or compensation under the Fatal Accidents Ordinance (Cap. 22 of the laws of Hong Kong), the Employees' Compensation Ordinance (Cap. 282 of the laws of Hong Kong), the Occupiers' Liability Ordinance (Cap. 314 of the laws of Hong Kong) or at common law by or in consequence of any accident or injury to any workman or other person whether in the employ of the Seller or in the performance of the Seller's obligations under the Contract (save and except liability for death or personal injury resulting directly from negligence of the Buyer) and the Seller shall indemnify and keep indemnified the Buyer against all claims, demands, proceedings, costs, charges and expenses whatsoever in respect of or in relation thereto.

13.2 In the event that any workman or other person in the employ of the Seller or engaged on any work done in pursuance of the Contract suffers any personal injury and whether there be a claim for compensation or not, the Seller shall within seven (7) days give notice in writing of such personal injury to the Buyer.

13.3 The Seller acknowledges and accepts that except for the liability for death or personal injury resulting directly from negligence of the Buyer under sub-clause 13.1 above, all other liabilities, potential or actual, of the Buyer are excluded to the maximum extent permitted by law.

14. Payment

14.1 Purchase Orders will be placed by individual Hospital. Payment in respect of the Goods supplied thereof shall be arranged by respective Hospital within 30 clear working days from the date of receipt of invoice or acceptance of Goods, whichever is the later, provided that the acceptance test can be carried out within 14 days from the date of delivery. In case the acceptance test is not carried out at the above specific date, the invoice would be settled by respective Hospital within 45 clear working days from the date of invoice.

14.2 Invoices and correspondence concerning payment must be forwarded to the relevant Hospital. The Authority shall not be held responsible for any delay in payment if invoices and correspondence concerning payment are not properly addressed.

14.3 No payment will be made unless:

(a) the Goods have been satisfactory tested; and
(b) the Seller has carried out its obligations under the Contract and/or Purchase Order with respect to the delivery for which an invoice relates.

15. Compliance with Other Requirements

The Seller shall during the Validity Period, comply with the MDACS Requirements, the EDI Requirements, the Cataloguing and Data Cleansing Requirements and the Order Records Requirements.

16. Corrupt Gifts

16.1 Sellers shall not, and shall procure that their employees, agents and sub-contractors shall not, offer, solicit or accept an advantage as defined in the Prevention of Bribery Ordinance (Cap. 201 of the laws of Hong Kong) in connection with this Contract.

16.2 If the Seller or any employee or agent of the Seller or its sub-contractor (if any) shall be found to have committed an offence under the Prevention of Bribery Ordinance (Cap. 201 of the laws of Hong Kong) for the time being in force or any subsidiary legislation made thereunder or under any law of a similar nature in relation to its Standing Quotation or any other Contract, the Buyer may terminate the Contract and/or the Purchase Orders or any other contract without entitling the Seller to any compensation therefor and the Seller shall indemnify the Buyer against all costs, claims, damages, losses and expenses necessarily incurred or suffered by the Buyer as a result therefrom.

17. Publicity

The Seller shall submit to the Buyer all advertising or other publicity material relating to the Standing Quotation or the Goods supplied or other work done in connection with the Contract wherein the name of the Buyer is mentioned or from which a connection with the Buyer can reasonably be inferred or implied. The Seller shall not publish or use any advertising or other publicity material relating to the Buyer or otherwise use or mention the name of the Buyer for any promotion or marketing purposes without the prior written consent of the Buyer. Nothing in this Contract expressly or impliedly constitutes an endorsement of any goods or services and each party agrees not to conduct itself in such a way as to imply or express any such approval or endorsement.

18. Confidentiality

18.1 The Seller undertakes that the Seller and its employees, agents or sub-contractors (if any) will keep in confidence and not disclose to any third party without the Buyer's prior written consent any information or data (whether of a commercial or technical nature or otherwise) acquired from the Buyer in connection with the Standing Quotation and/or the Contract other than disclosure to those persons to whom it is necessary to supply such information to enable performance of the Standing Quotation and/or the Contract (as the case may be). The Seller shall not use the expertise evident therein in any manner detrimental to the interests of the Buyer.

18.2 Nothing contained above shall apply to prevent the Seller from disclosing any information:

(a) in its possession (with full right to disclose) prior to receiving it from the Buyer;
(b) which is or later becomes public knowledge other than by breach of this Clause; or
(c) which it may independently develop or receive from a third party (with full right to disclose).

18.3 Upon the expiry or termination of the Standing Quotation or the Contract, the Seller shall return to the Buyer and shall not retain any copy of any confidential documents and materials which have been supplied by the Buyer to the Seller to enable performance of the Standing Quotation or the Contract (as the case may be).

19. Termination

19.1 The Contract and the Standing Quotation will expire automatically, without notice being necessary, on expiry of the Validity Period.

19.2 Without prejudice to any other rights or remedies of the Buyers under the Contract or at law, the Buyer may at any time by notice in writing terminate the Contract and/or any Purchase Orders, without entitling the Seller to compensation, if:

(a) the Seller commits a breach of any of the T&Cs (and, if such breach is capable of remedy, fails to remedy the breach within 14 days of receiving notice from the Buyer party specifying the breach and requiring the breach to be remedied);
(b) becomes insolvent within the meaning of any applicable law; or
(c) pursuant to a Safety Alert Notice or a Product Recall Notice having been issued by the Seller to the Buyer.

19.3 The Buyer may also at any time by not less than 30 days' prior written notice terminate the Contract and/or any Purchase Orders.

19.4 If the Buyer terminates the Contract in accordance with sub-clauses 19.2 and 19.3 of these T&Cs above, the Buyer may consider the Seller to be a prohibited seller for the purposes of any procurement exercise (including future Invitation to Quote) of the Buyer.

19.5 Termination shall be without prejudice to any right or action or remedy which shall have accrued or shall accrue thereafter to the Buyer.

19.6 Those terms of this Contract which by their nature should survive termination of this Contract shall survive. Such clauses shall include without limitation, Clauses 10, 11, 12, 13 and 18 of these T&Cs.

20. Personal Data

20.1 The Buyer may require that certain personal data or information of the Seller, its staff, agents and sub-contractors (if any) be provided by the Seller.

20.2 Any such personal data will be used for purposes relating to the Standing Quotation and/or the Contract. If insufficient or incorrect information is provided, the Buyer may terminate this Contract and/or Purchase Orders for breach in accordance with Clause 19 of these T&Cs.

20.3 The personal data provided by the Seller may be disclosed to the Government of Hong Kong, regulatory authorities or parties responsible for overseeing the Standing Quotation and/or the Contract and/or any other contract, evaluating the Seller in relation to this Contract, and to comply with legal obligations of the Buyer.

21. Force Majeure

21.1 Neither the Seller nor the Buyer shall be liable to the other, or be deemed to be in breach of its obligations under a Contract and/or Purchase Orders, by reason of any delay in performing, or any failure to perform, any of its obligations thereunder if the delay or failure was beyond that party's reasonable control. Without prejudice to the generality of the foregoing, the following shall be regarded as causes beyond either party's reasonable control:

(a) act of God, explosion, flood, tempest, fire or accident;
(b) war or threat of war, sabotage insurrection or civil disturbance;
(c) ordinances, regulations, by-laws, or prohibitions of any kind on the part of any governmental authority.

21.2 Any party affected by an event of force majeure shall notify the other in writing forthwith, and each party's obligations shall be suspended during the continuance of such event of force majeure. In the event that such event of force majeure continues for one (1) month or more, then the party not affected by such event may terminate such Contract and/or Purchase Order without liability to the non-terminating party.

22. Applicable Law

22.1 The validity and interpretation of this Contract and/or the Purchase Orders shall be governed in all respects by the laws of Hong Kong.

22.2 The Seller shall comply with all applicable international and local laws, rules and regulations pertinent to its obligations under this Contract.

23. Contracts (Rights of Third Parties) Ordinance

The application of the Contracts (Rights of Third Parties) Ordinance is expressly excluded and no person who is not a party to this contract shall be entitled to enforce any right or term of this contract pursuant to the Contracts (Rights of Third Parties) Ordinance.

24. Conflict of Interest

24.1 The Seller shall on appointment and during the Term and for six (6) months thereafter:

(a) immediately declare any actual, apparent, potential or perceived Conflict of Interest that will, or might, arise in respect of the provision of the Services or the performance of its obligations under the Contract, including but not limited to any interest or association, the Seller, its Associated Persons may have with any contractors, suppliers or sub-contractors related to this Contract, directly or indirectly; and

(b) forthwith notify the Authority in writing and keep the Authority notified of all or any facts which may reasonably be considered to give rise to a Conflict of Interest.

24.2 The Seller shall render its advice or recommendations pursuant to this Contract to the Authority on an impartial basis without giving favour to any particular service, equipment or product in which the Seller has a direct or indirect commercial interest. The Seller shall obtain from each and every one of its Directors, employees, agents and sub-contractors who are involved in this Contract a written undertaking to observe this sub-clause and sub-clause 24.3 below.

24.3 The Seller shall require its Directors, employees, agents and sub-contractors involved in this Contract to declare in writing to the Authority and keep the Authority informed regularly of any actual, apparent, potential or perceived Conflict of Interest, including but not limited to all or any facts which may reasonably be considered to give rise to a Conflict of Interest. In the event that any Conflict of Interest becomes known to the Seller or any of its Directors, employees, agents and sub-contractors involved in this Contract and / or is disclosed in a declaration, the Seller shall forthwith take such measures as are necessary to mitigate as far as possible or to remove the Conflict of Interest so disclosed.

24.4 The Seller shall prohibit its Directors and employees who are involved in this Contract from engaging in any work or employment other than in the performance of this Contract, with or without remuneration, which could give rise to any actual, apparent, potential or perceived Conflict of Interest. The Seller shall procure that its agents and sub-contractors impose similar restrictions on their Directors and employees by way of a contractual provision.

24.5 The Seller shall take all necessary measures (including by way of contractual provisions where appropriate) to ensure that its Directors, employees, agents and sub-contractors who are involved in this Contract are aware of the provisions under Sub-clause 24.2 to the Sub-clause 24.4 above. Where the Seller has obtained the Authority's written approval to appoint sub-contractors to undertake any part of the Services, the Seller shall take all necessary steps to procure and ensure that the same covenants in this Clause are imposed on the sub-contractors and shall take all necessary steps to enforce such covenants.

24.6 In this Clause 24:

(a) "Associated Company" in relation to the Seller means any company which is the holding company or subsidiary company or sister company of the Seller. A 'sister company' means a company which belongs to the same holding company as the Seller's;

(b) "Associate Person" or "Related Person" means:

- the Directors, employees, agents and sub-contractors of the Seller (and if the Seller is a partnership, any of the members/partners of that partnership) who are or will be involved in the Quotation, the Standing Quotation Submission, the provision of the Services or the performance of the Seller's obligations under the Contract;

- any person or entity (i) which has Control, directly or indirectly, over the Seller; (ii) which is Controlled, directly or indirectly, by the Seller; or (iii) which is Controlled by, or has Control over, a person/entity referred to in (i) or (ii); and

- (i) any member of a partnership in which of the Seller is a member or (ii) any company one or more of whose Directors is in common with one or more of the Directors of the Seller.

(c) "Control" or Controlled" means

- the possession by one person, directly or indirectly (through one or more intermediaries) of the power (whether holding office as Director or otherwise) to affect, secure, direct and / or cause the direction of the management, affairs or policies of another person;

- with respect to a corporation, partnership or other body corporate, such power in (a) above may be evidenced by (but is not limited to) that person: (i) holding shares or interests or possessing voting power in or in relation to that or any other person such as, but not limited to, the right to exercise, directly or indirectly, more than fifty percent (50%) of the voting rights attributable to the shares of or interest in such corporation, partnership or other body corporate; and / or (ii) having powers conferred on that person by any constitution, memorandum or articles of association, partnership, agreement or arrangement (whether legally enforceable or not);

(d) "Conflict(s) of Interest" shall include (but are not limited to) (a) any situation where the personal, financial, commercial or other interest of the Seller or any of its Related Persons, conflict or compete, or may be expected to conflict or compete, with the Seller's duties to the Authority under the Contract; and (b) any situation where the Seller or any of its Related Persons may have any person, financial, commercial or other interests in any potential service, advice, proposals or recommendations made or which may be made by the Seller under the Contract;

(e) "Director" means any person occupying the position of director by whatever name called and without limitation a de facto or shadow director;

24.7 Notwithstanding any provisions in this Clause, the restrictions in this Clause shall not prohibit the holding (directly or through nominees) of investments in companies which investments are listed on any stock exchange provided that such investments do not exceed 5 per cent of the issued shares of any one company.

25. Admission of Seller Personnel to HA Premises

25.1 Upon request from time to time by HA, the Seller shall provide to HA a list of the names, posts, staff identity card numbers, addresses and telephone numbers of all Seller's employees, agents, sub-contractors and those employees and agents of the aforementioned sub-contractors (collectively "Relevant Personnel") who may at any time require admission on behalf of the Seller to any premises owned, managed, controlled or occupied by HA ("HA premises") for the purposes of the Contract if so required by the HA's/Authority Representative and in that event such list shall specify the capacities in which those persons are employed by or connected with the Seller and shall contain such other particulars as the HA's/Authority Representative may reasonably require.

25.2 The Seller shall ensure that while any of the Relevant Personnel is on HA premises, they shall observe HA's rules, regulations, guidelines and code of practice which are from time to time applicable to the Seller's execution of all or any part of the services at the HA premises.

25.3 The Seller shall obtain from all Relevant Personnel consent to disclose and/or submit to HA their personal data for the purposes of the provisions of this Clause 25 and other provisions of the Contract.

25.4 The HA's/Authority Representative reserves the right to refuse to admit to the HA premises, or the right to evict from the HA premises, any person, whose admission would be, in the reasonable opinion of the HA's/Authority Representative, undesirable.

25.5 In the event that the Seller fails to comply with this Clause 25 and it is determined that such failure is prejudicial to the interests of HA, the HA's/Authority Representative may thereupon terminate the Contract.

25.6 Without prejudice to any other provision of the Contract, the Seller shall indemnify and keep indemnified HA against all losses, claims, costs, demands and expenses that may arise out of or in consequence of any breach of this Clause 25.

25.7 The Seller acknowledges and agrees that:

(a) HA may at any time vary unilaterally the entry requirements (including any vaccination and/or testing requirements) to any HA premises;

(b) it will comply with the guidelines and/or directions issued by HA from time to time on entry requirements (including any vaccination and/or testing requirements) to the HA premises.

26. The Sale of Goods (United Nations Convention) Ordinance (Cap. 641 of the Laws of Hong Kong)

The Authority and the Seller agree that the provisions of the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Contract.

27. Listing under the Medical Device Administrative Control System

27.1 The Seller shall, upon request from the Authority, update the Authority the listing record of the Goods which are applicable MDs under MDACS and/or status of its submissions to DH for listing of such Goods under MDACS. If, in the sole opinion of the Authority, the Seller fails to submit its application(s) to DH before the committed date provided in accordance with **Clause 7.3 of Part I (Terms of Standing Quotation)** or the MDACS listing cannot be completed within twelve (12) months after contract commencement or the Seller's declaration under **Clause 3 in Schedule B** is found to be invalid, incorrect or unsubstantiated, the Authority may, without prejudice to the Authority's other rights and remedies under the contract or by law, in its absolute discretion,

(i) reject all or part of the Goods which fail to meet any of the above requirements (or those which the Seller fails to demonstrate compliance with the above requirements) ("Relevant Goods") delivered hereunder (notwithstanding any acceptance or deemed acceptance of the Relevant Goods by the Authority or the making of payment by the Authority);

(ii) cancel, or suspend the performance of, any order placed by the Authority for the Relevant Goods which is not yet delivered;

(iii) delete the Relevant Goods from the Contract (if the Contract is awarded with more than one item) such that the Authority shall not be obliged to order a minimum quantity of the Relevant Goods with the Seller during the term of the Contract notwithstanding any provision contained in the Contract; and/or

(iv) terminate the Contract forthwith.

27.2 The Seller agrees to comply with all statutory requirements within the prescribed period under the legislation should the statutory control of medical devices takes effect. The Seller shall demonstrate to the Authority its compliance with the statutory requirements upon request by the Authority. If the Seller fails to comply with any statutory requirement or demonstrate compliance of the same, and without prejudice to the Authority's other rights and remedies provided under this Contract or otherwise according to law, the Authority shall have the options set out in Clause 27.1 above, and reference to "Relevant Goods" shall be construed to include

the Goods which fail to meet any statutory requirement (or those which the Seller fails to demonstrate compliance with the statutory requirements).

27.3 Any monies paid by the Authority to the Seller in respect of the Relevant Goods which have been rejected, pursuant to Clauses 27.1 and/or 27.2 above, shall be refunded to the Authority and the Authority may purchase from other sources alternate supplies to substitute for the Relevant Goods rejected and those which, but for the deletion of the Relevant Goods from the Contract or the termination of the Contract, would be supplied by the Seller to the Authority under the Contract, and the Seller must, on demand by the Authority, pay to the Authority the additional costs and expenses in obtaining such alternate supplies, including but not limited to price difference and related freight and delivery charges.

28. National Security

28.1 The Seller shall not engage in acts or activities that are likely to constitute or cause the occurrence of offences endangering national security or which would otherwise be contrary to the interest of national security.

28.2 The Authority may immediately terminate the Contract upon the occurrence of any of the following events:

(a) the Seller has engaged or is engaging in acts or activities that are likely to constitute or cause the occurrence of offences endangering national security or which would otherwise be contrary to the interest of national security;
(b) the continued engagement of the Seller or the continued performance of the Contract is contrary to the interest of national security; or
(c) the Authority reasonably believes that any of the events mentioned above is about to occur.

28.3 In the event that the Contract is terminated in accordance with Clause 28.2 above, the Seller shall be liable for and shall indemnify and keep indemnified the Authority against, all losses, damage, costs and expenses incurred by the Authority arising out of or in relation to the termination.

28.4 In the event that the Contract is terminated in accordance with Clause 28.2 above, the Authority shall not be responsible for any claim, legal proceeding, liability, loss (including any direct or indirect loss, any loss of revenue, profit, business, contract or anticipated saving), damages (including any direct, special, indirect or consequential damages of whatsoever nature) or any cost or expense, suffered or incurred by the Seller arising out of or in relation to the termination.

29. General

29.1 This Contract is personal to the Seller and the Seller shall not assign, transfer, sub-contract or purport to assign, transfer or sub-contract to any other person any of its rights, or sub-contract any of its obligations, under the Contract and/or the Purchase Order.

29.2 This Contract and/or the Purchase Order(s) and all their rights and obligations may be assigned or transferred by the Buyer.

29.3 The Seller shall be an independent contractor and nothing herein shall be taken to constitute a partnership between the parties or the appointment of one of the parties as agent or employee of the other.

29.4 Any notice or document to be given under the Contract shall be in writing and shall be left at or sent by prepaid post or facsimile transmission to the registered office for the time being of the party to be served or to such other address and/or number as may have been last notified in writing by such party to the other party. Any such notice or document shall be deemed to have been duly given at the time of delivery (if given by hand) or on the third (3rd) day after posting (if given by prepaid post) or immediately upon transmission with confirmatory answerback (if given by facsimile).

29.5 No waiver by the Buyer of any breach of the Contract and/or Purchase Orders by the Seller shall be considered as a waiver of any subsequent breach of the same or any other provision.

29.6 Any variation to these T&Cs or any terms of a Contract shall be binding only if it is recorded in a document signed by both parties.

29.7 If any provision of these T&Cs and/or a Purchase Order is held by any court or competent authority to be invalid or unenforceable in whole or in part, the validity of the other provisions of these T&Cs and/or a Purchase Order (as the case may be) and the remainder of the provision in question shall not be affected thereby.

Schedule A
Details of Offered Goods and Price

(Pages 41 to 42)

Please complete all required details in the Excel File

Supply of Surgical Stapler for Endoscopic Surgery Under Nominated Product Scheme
Schedule A (Price)
Standing Quotation

Group No.	Classification of Goods	Brand	Model No (see Note 1 & Note 2)	Product Details / Description (Series, Size, Feature as appropriate)	Name of Manufacturer	HA Item Code (if known)	UOM (ea or box)	Currency	NPS Unit Price	Packing (i.e. 5/10 per box)	Delivery Lead Time (days)	Country of Origin	Universal Product Number (UPN)	UPN Type (i.e. EAN, HIBC)	Shelf Life (Year)	Submission of Past 18-month Consumption Record (HA or equivalent in the HKSAR or elsewhere) (see Note 3)			MDACS			Whether Included in other HA Contract	Product Specific Standard applicable to the offered product (see Clause 2.2(a) of Part II)	Compliance with the standard quoted in Column Y	Sterilization Information			
																Yes / No	Reference No.	Country (See Note 4)	Risk Level (I/II/III/IV/ N/A)	MDACS listing no. (if any & applicable)	Validity of Certificate (from - to) (DD/MM/YY)	Yes / No	Product Specific Standard / Not Applicable	Comply / Not Comply / Not Applicable	Sterile Item (Yes / No)	Name of Sterilization Company/ Service Provider	Address of Sterilization Company/ Service Provider	Relationship between Manufacturer and Sterilization Company/ Service Provider (e.g. in-house / outsourced)
1	Surgical Stapler for Endoscopic Surgery, Straight																											
2	Surgical Stapler for Endoscopic Surgery, Articulating																											

Remarks: Note 1 : One line should consist one item only. Please add rows / worksheets if necessary.
Note 2 : If model number is not available, please input the vendor catalogue number.
Note 3 : Clause 2.1 of Part II refers. Please indicate reference numbers (HA PO number or attachment numbers for non-HA consumption record) for easy reference. Only one Record per series is needed (for items of the same series, please refer to the corresponding reference number). HA is not bound to accept any new offers without proven consumption record.
Note 4 : For consumption records from non-HA hospitals, please indicate the country concerned.
Note 5 : Completed Standing Quotation Form [including Schedule A (Price) in excel format] in Both Hard Copy and Soft Copy (i.e. in CD-Rom) accompany with the supporting documents are required to be returned in a plain sealed envelope and lodged to the Tender Box on or before the Standing Quotation Closing Date and time as stipulated under Standing Quotation Invitation / Advertisement. Should there be any information discrepancy between the hard copy and soft copy, the Authority will only accept the offers as printed in the hard copy that lodged and opened by the HA Tender Opening Committee.

Person Authorized to Sign Standing Quotation

Name of Seller : _____ **Name :** _____ **Authorized Signature :** _____

Seller's Chop : _____ **Position Held :** _____ **E-mail Address :** _____

Date: _____ **Telephone No. :** _____ **Facsimile No. :** _____

Supply of Surgical Stapler for Endoscopic Surgery Under Nominated Product Scheme
Schedule A (Price)
Standing Quotation

Group No.	Classification of Goods	Brand	Model No (see Note 1 & Note 2)	Product Details / Description (Series, Size, Feature as appropriate)	Name of Manufacturer	HA Item Code (if known)	UOM (ea or box)	Currency	NPS Unit Price	Packing (i.e. 5/10 per box)	Delivery Lead Time (days)	Country of Origin	Universal Product Number (UPN)	UPN Type (i.e. EAN, HIBC)	Shelf Life (Year)	Submission of Past 18-month Consumption Record (HA or equivalent in the HKSAR or elsewhere) (see Note 3)			MDACS			Whether Included in other HA Contract	Product Specific Standard applicable to the offered product (see Clause 2.2(a) of Part II)	Compliance with the standard quoted in Column Y	Sterilization Information			
																Yes / No	Reference No.	Country (See Note 4)	Risk Level (I/II/III/IV/ N/A)	MDACS listing no. (if any & applicable)	Validity of Certificate (from - to) (DD/MM/YY)	Yes / No	Product Specific Standard / Not Applicable	Comply / Not Comply / Not Applicable	Sterile Item (Yes / No)	Name of Sterilization Company/ Service Provider	Address of Sterilization Company/ Service Provider	Relationship between Manufacturer and Sterilization Company/ Service Provider (e.g. in-house / outsourced)
3	Surgical Stapler for Endoscopic Surgery, Articulating, Powered-driven																											
4	Staple (Loading Unit) and related accessories																											

Remarks:
Note 1 : One line should consist one item only. Please add rows / worksheets if necessary.
Note 2 : If model number is not available, please input the vendor catalogue number.
Note 3 : Clause 2.1 of Part II refers. Please indicate reference numbers (HA PO number or attachment numbers for non-HA consumption record) for easy reference. Only one Record per series is needed (for items of the same series, please refer to the corresponding reference number). HA is not bound to accept any new offers without proven consumption record.
Note 4 : For consumption records from non-HA hospitals, please indicate the country concerned.
Note 5 : Completed Standing Quotation Form [including Schedule A (Price) in excel format] in Both Hard Copy and Soft Copy (i.e. in CD-Rom) accompany with the supporting documents are required to be returned in a plain sealed envelope and lodged to the Tender Box on or before the Standing Quotation Closing Date and time as stipulated under Standing Quotation Invitation / Advertisement. Should there be any information discrepancy between the hard copy and soft copy, the Authority will only accept the offers as printed in the hard copy that lodged and opened by the HA Tender Opening Committee.

Person Authorized to Sign Standing Quotation

Name of Seller : _____ **Name :** _____ **Authorized Signature :** _____

Seller's Chop : _____ **Position Held :** _____ **E-mail Address :** _____

Date: _____ **Telephone No. :** _____ **Facsimile No. :** _____

Schedule B
Schedule of Compliance

Sellers shall provide without any omission the following information in respect of their offers.

1. Particulars of Offer

(a) Country of Origin : _____
(Substantial place of manufacture of goods)

(b) Name and Address of Manufacturer:

Name: _____
Address: _____

(c) Name and Address of Manufacturing facility/site of offered Goods [if different from 1(b)]:

Name: _____
Address: _____

(d) Business Relationship between Seller and the Manufacturer : _____

(e) License / Test Certificate / Report concerning product safety (if applicable):

_____

2. Electronic Data Interchange (EDI) Requirement

( ) I/We confirm I am / we are able to comply with the Electronic Data Interchange (EDI) Requirement as required under Part II – Quotation Subject Matter.

OR

( ) I am / We are not ready to comply with the EDI requirement but commits to install the facility within 3 months from the commencement date of the Validity Period.

(Please put a tick as appropriate)

Person Authorized to Sign Standing Quotation

Name of Seller : _____	Name : _____	Authorized Signature : _____
Seller's Chop : _____	Position Held : _____	E-mail Address : _____
Date : _____	Tel. No: _____	Fax No.:_____

3. Listing under the Medical Device Administrative Control System

I/We confirm that:

(a) The following medical device(s) under offer is/are already listed under the MDACS with the following details:-

Medical device under offer (Manufacturer, Brand and Model)	Listing number issued by the DH	Validity of the MDACS certificate		Device Description under MDACS
		(From)	(To)	

(b) The following medical device(s) under offer **has/have been** submitted to the Medical Device Division (MDD) under DH for listing under the MDACS on the following date(s):-

Medical device under offer (Manufacturer, Brand and Model)	Actual date of submission to DH	Application reference number provided by DH

I / We also confirm that the information and supporting documents provided under the "Checklist for Medical Devices to be Listed under MDACS" in the Appendix I to this Schedule B are accurate and not misleading.

Person Authorized to Sign Standing Quotation

Name of Seller : _____ Name : _____ Authorized Signature : _____

Seller's Chop : _____ Position Held : _____ E-mail Address : _____

Date : _____ Tel. No: _____ Fax No.:_____

(c) The following medical device(s) under offer **will be** submitted to the Medical Device Division (MDD) under DH for listing under the MDACS by the following date(s):-

Medical device under offer (Manufacturer, Brand and Model)	Planned date of submission to DH (a date not later than 6 months after contract commencement)

I / We also confirm that the information and supporting documents provided under the attached "Checklist for Medical Devices to be Listed under MDACS" in the Appendix I to this Schedule B are accurate and not misleading.

(d) The following medical device(s) under offer are not applicable MDs according to the classification rules of MDs under MDACS or are otherwise not subject to listing under the MDACS. The reasons are provided below and the relevant supporting documents are attached:

Medical device under offer (Manufacturer, Brand and Model)	Reason(s) of MDACS Listing being inapplicable (with supporting documents) (For example: Class I of general MDs or Class A in-vitro diagnostic MDs according to the classification rules of MDs under MDACS)

(e) I / We agree to comply with all statutory requirements within the prescribed period under the legislation should the statutory control of medical devices takes effect and will demonstrate to the Authority my / our compliance with the statutory requirements upon request by the Authority.

Person Authorized to Sign Standing Quotation

Name of Seller : _____ Name : _____ Authorized Signature : _____

Seller's Chop : _____ Position Held : _____ E-mail Address : _____

Date : _____ Tel. No: _____ Fax No.:_____

Appendix I of Schedule B

Checklist for Medical Devices to be Listed under MDACS

(Note to Sellers: Please complete this part if the offered product(s) fall within Clause 3(b) or (c) of Schedule B. The information provided by successful Sellers(s) in this part will be passed to MDD under DH for reference. Sellers shall note that HA does not play any part in the MDACS listing application process and any onward transmission of these documents to DH does not imply any endorsement of the content of these information and supporting documents by HA. In order to initiate and complete the application process for MDACS listing, Sellers are required to make formal application and submission of the required supporting documents with/to DH direct.)

Pursuant to Clause 3 of Schedule B, I/we confirm that my/our medical device(s) under offer which has/ have been or will be submitted to the MDD under DH and submit the attached supporting documents in this connection:-

The confirmation below is applicable to Standing Quotation items [please specify the Standing Quotation item numbers] _____ to _____quoted in Schedule A (Price). Separate new sheet(s) is/are added for other items or different manufacturers for same item description, if applicable.

Standing Quotation Reference	NPS24-005
Standing Quotation Subject	Invitation to Quote for the Supply of Surgical Stapler for Endoscopic Surgery
Manufacturer of Standing Quotation items	
Application Reference No. provided by DH (if available)	

( ) Please tick "√" as appropriate N.A. = Not Applicable

Compliance ***(Please insert Comply / Not Comply / N.A.)***	**Supporting Document Submitted**	**Please indicate the Page No. of information provided**	**Checklist Item No.**	**Information / Document**	**Explanatory Notes**
( )	( )		1.1	Quality Management System certificate	Established Quality Management System (e.g. ISO 13485, GB/T 42061) for the Manufacturer.
( )	( )		1.2	Provision of accessories or consumables (if applicable)	Information tabulated, or in equivalent format, describing available accessories or consumables compatible to the medical device.
( )	( )		1.3	Provision of maintenance services (if applicable)	Information tabulated, or in equivalent format, describing concerned services provided by the supplier, the Local Responsible Person (LRP), or available in Hong Kong.
( )	( )		2.1	Brand, model and product code	Product identifier of the medical device

( )	( )		2.2	Intended use	The specific claim made by the Manufacturer about the designated way of use and intended outcome of using the device.
( )	( )		2.3	Sterility (if applicable)	Information stating the device is supplied sterile or can be re-sterilized.
( )	( )		2.4	Instructions for Use	The instructions for use, also known as user manual, in paper form or other style that is supplied with the medical device to inform user of the device's proper use and precaution to be taken.
( )	( )		2.5	Package labeling	Package labeling indicating necessary information, e.g. contact, warning signs, sterility, etc. to provide a clear overview and identification of device.
( )	( )		2.6	Risk analysis report/summary (if applicable)	Report or summary in the format of Failure Modes and Effects Analysis (FMEA), Fault Tree Analysis, etc. to assess and mitigate foreseeable risk. The clinical benefit shall outweigh the residual risk to be satisfactory.
( )	( )		2.7	Technical report (if applicable)	Technical assessment reports or certificates usually in engineering sense about tests and verifications conducted to demonstrate the Safety, Quality and Performance of the Device, e.g. laboratory certificate of IEC60601-1: Safety requirements for medical electrical systems
( )	( )		2.8	Availability of Marketing approval	Marketing approval from jurisdictions outside Hong Kong, such as Mainland China (approval from National Medical Products Administration), member countries of European Union that have implemented relevant EU directives or regulations, United States of America (approval from U.S. Food and Drug Administration), etc.

( ) Please tick "√" or insert "N/A" where appropriate N/A = Not Applicable

Person Authorized to Sign Standing Quotation

Name of Seller : _____ Name : _____ Authorized Signature : _____

Seller's Chop : _____ Position Held : _____ E-mail Address : _____

Date : _____ Tel. No: _____ Fax No.:_____

4. Cataloguing and Data Cleansing

( ) I am/We are willing to provide technical support to the Authority in development of item catalogues and data cleansing of the offered products in accordance with the Authority's policy and procedures.

(Please put a tick as appropriate)

5. Operational Training

I/We confirm that the following operational trainings will be provided to Authority Representatives.

( ) Local briefing upon request.

( ) Formal local training (course outline attached).

(Please put a tick as appropriate)

6. Order Records

( ) I/We confirm to provide quarterly (every three months) report to the Authority on the purchase order history of both Goods that are (a) listed and (b) not listed in the Standing Quotation. The report shall include details such as order number, date, hospital name, ordering quantity, value and model number, etc.

(Please put a tick as appropriate)

7. Seller's Code of Conduct

Pursuant to Clause 18 of Part I (Terms of Standing Quotation) in relation to the prevention of bribery and the Seller's code of conduct, Sellers are required to submit its codes of conduct applicable to its staff. The "Sample Code of Conduct for NGO/ Private Sector" issued by the Independent Commission Against Corruption ("ICAC") is accessible through the HA website under "Tender Notice" below for Seller's reference:

http://www.ha.org.hk/visitor/ha_visitor_index.asp?Content_ID=2001&Lang=ENG&Dimension=100

Person Authorized to Sign Standing Quotation

Name of Seller : _____	Name : _____	Authorized Signature : _____
Seller's Chop : _____	Position Held : _____	E-mail Address : _____
Date : _____	Tel. No: _____	Fax No.:_____

8. Payment Discounts

I/We provide below the discount that I/we will allow on the offered price(s) if payment for each consignment is made in full within:

(a) 7 calendar days from date of receipt of invoice or from date of acceptance of goods, whichever is the later : _____ % discount.

(b) 8 to 14 calendar days from date of receipt of invoice or from date of acceptance of goods, whichever is the later : _____ % discount.

Acceptance of Goods shall be construed within the meaning of Clause 4.2 of Part III (Terms and Conditions).

N.B.: Sellers are requested to insert the word 'NIL' in the spaces provided above if no payment discount is offered.

9. Ordinances Concerning Product Safety

I/We confirm that :-

(a) Licence(s) for the provision of the offered product:-
( ) is required under the Chapter _____ of Hong Kong Ordinance and a copy of which is attached.
( ) is not required.

(b) Test certificate/report for the provision of the offered product is required and a copy of which:-
( ) is attached.
( ) will be completed and submitted during acceptance of goods.

(c) ( ) Test certificate/report for the provision of the offered product is not required.

(d) The Authority * is required / is not required to maintain the licence(s) / test certificate(s) for the possession or use of the offered product.

(Please put a tick in ( ) and delete * as appropriate)

Person Authorized to Sign Standing Quotation

Name of Seller : _____	Name : _____	Authorized Signature : _____
Seller's Chop : _____	Position Held : _____	E-mail Address : _____
Date : _____	Tel. No: _____	Fax No.:_____

10. Certificate of Non-Collusion

I/We certify that this is a bona fide Standing Quotation, and that I/we have not fixed or adjusted the amount of the Standing Quotation by or under or in accordance with any agreement or arrangements with any other person. I/We also certify that I/we have not done and I/we undertake that I/we will not do at any time before the date of notification of acceptance of this Standing Quotation any of the following acts:

(a) Communicate to any person other than the person calling for those Standing Quotations the amount or approximate amount of the proposed Standing Quotation, except where the disclosure, in confidence, of the approximate amount of the Standing Quotation was necessary to obtain insurance premium quotations required for the preparation of the Standing Quotation;

(b) Enter into agreement or arrangements with any other person that he shall refrain from tendering or as to the amount of any Standing Quotation to be submitted;

(c) Offer or pay or give or agree to pay or give any sum of money or valuable consideration directly or indirectly to any person for doing or having done in relation to any other Standing Quotation or proposed Standing Quotation any act or thing of the sort described above.

In this certificate, the word "person" includes any person and any body or association, corporation or unincorporated, and "any agreement or arrangement" includes any such transaction, formal or informal, and whether legally binding or not.

I/We expressly acknowledge and agree that, without prejudice to any other rights of the Authority, if this certification is in anyway incorrect, or becomes incorrect prior to the award of this Standing Quotation, the Authority may:

(i) disqualify my/our Standing Quotation from consideration;

(ii) withdraw any confirmation of award of Standing Quotation already made, without penalty or liability;

(iii) disqualify me/us, our holding company and subsidiaries from participation in any future Standing Quotations issued by the Authority for such period as the Authority may in its entire discretion consider appropriate;

(iv) take such other actions, including reporting me/us to the government or regulatory authorities in Hong Kong or elsewhere, as the Authority considers appropriate.

Person Authorized to Sign Standing Quotation

Name of Seller : _____	Name : _____	Authorized Signature : _____
Seller's Chop : _____	Position Held : _____	E-mail Address : _____
Date : _____	Tel. No: _____	Fax No.:_____

11. Personal Data (Privacy) (Amendment) Ordinance 2021

I/we certify the following:-

(a) I shall/We will and shall/will procure my/our employees, agents or representatives to comply with the provisions of the Personal Data (Privacy) Ordinance (Cap. 486 of the Laws of Hong Kong) (the "Ordinance") (including any amendments thereon from time to time), and any applicable codes of practice, guidance notes or regulations in the handling of personal data (as defined in the Ordinance from time to time) ("Personal Data") collected by and provided to me/us for the purpose of this Invitation to Quote/Contract.

(b) I/We shall not keep Personal Data longer than is necessary for the fulfilment of the purpose (including any directly related purpose) for which the same are or to be used. I shall/we will:

(i) return, destroy or permanently erase all such Personal Data;
(ii) destroy or permanently erase all copies of such Personal Data made by me/us; and
(iii) use all reasonable endeavours to ensure that anyone who has received any such Personal Data destroys or permanently erases such Personal Data and any copies made by it or him,

in each case, save to the extent that I am/we or the recipients are required to retain any such Personal Data by any applicable law, rule or regulation or by any competent judicial, governmental, supervisory or regulatory body.

(c) I shall/We will take all practical steps and have in place and maintain appropriate security measures to prevent unauthorised or accidental access, processing erasure, loss or use of Personal Data collected by or transferred to it having particular regard to:

(i) the kind of Personal Data and the harm that could result if any of those things should occur;
(ii) the physical location where the Personal Data are stored;
(iii) any security measures incorporated (whether by automated means or otherwise) into any equipment in which the Personal Data are stored;
(iv) any measures taken for ensuring the integrity, prudence and competence of persons having access to Personal Data; and
(v) any measures taken for ensuring the secure transmission of Personal Data.

Person Authorized to Sign Standing Quotation

Name of Seller : _____	Name : _____	Authorized Signature : _____
Seller's Chop : _____	Position Held : _____	E-mail Address : _____
Date : _____	Tel. No: _____	Fax No.:_____

12. Compliance with Radiation Ordinance (Cap. 303 of the laws of Hong Kong)

Sellers shall declare their offered product(s) the compliance with Radiation Ordinance (Cap. 303) with details as below:

I/We confirm that:-

( ) The offered product(s) contain(s) radioactive substances (RS).
( ) The offered product(s) do(es) not contain any radioactive substances (RS).

( ) The offered product(s) is an / are irradiating apparatus(es). (IA)
( ) The offered product(s) is not / are not irradiating apparatus(es). (IA)

If the offered product is IA or contain any RS, I/we confirm/commit to the following:-

( ) I/We have obtained the necessary license from Radiation Board for selling the offered RS/IA product in Hong Kong, **or**

( ) I shall/We will obtain the necessary license from Radiation Board for selling the offered RS/IA product in Hong Kong.

Seller is required to provide the information of the offered IA/RS product in below space (e.g. type, activity, etc.), if applicable :-

_____
_____
_____
_____

[Please refer to Hong Kong Radiation Ordinance (Cap. 303 of the laws of Hong Kong) for the definition of RS and IA]

(*Please tick "✓"where appropriate)

13. Minamata Convention on Mercury

( ) I/We confirm I/we have the intention to comply with the Minamata Convention on Mercury in the offered products.

Person Authorized to Sign Standing Quotation

Name of Seller : _____	Name : _____	Authorized Signature : _____
Seller's Chop : _____	Position Held : _____	E-mail Address : _____
Date : _____	Tel. No: _____	Fax No.:_____

14. National Security

(a) I/We confirm that, before I/We sign this undertaking, I/We have read and fully understand this undertaking, Clause 26 of Part I (Terms of Standing Quotation), and Clause 28 of Part III (Terms and Conditions) on "National Security".

(b) I/We, represent and warrant that I/We have not engaged, am/are not engaging and will not engage in acts or activities that are likely to constitute or cause the occurrence of offences endangering national security or which would otherwise be contrary to the interest of national security.

(c) I/We shall indemnify and keep indemnified the Authority against all losses, damages, costs or expenses arising out of or in relation to any breach of any of the representations and/or warranties above, including but not limited to damages for delay, costs and expenses of re-tendering and other costs incurred.

Person Authorized to Sign Standing Quotation

Name of Seller : _____	Name : _____	Authorized Signature : _____
Seller's Chop : _____	Position Held : _____	E-mail Address : _____
Date : _____	Tel. No: _____	Fax No.:_____

Schedule C

Instructions provided by the Seller for storage and handling of the Goods under the Consignment Stock Scheme

Schedule D

Order Records Report

NPS Contract no.	PO No.	PO Date	Hospital Name	Department	HA Item Code	HA Item Description	Model No.	Serial No.	Batch No.	Order Quantity	UOM	Unit Price (HKD)	Total Amount (HKD)

Name of Seller: _____

Agreement No.: _____

Report for the month of: _____

Schedule E

On-Loan Instruments Provided to Hospital Authority on a Free of Charge Basis

(Please submit all required details in Excel File)

Schedule F

Details of the safety alert system and product recall system

The Seller must also provide the names, email addresses and telephone numbers of the representatives of the manufacturer and (in case the Seller is a local distributor) the Seller with whom the Authority can contact in the event of Safety Alert Notice or Product Recall Notice.

Schedule G

Declaration of Conflict of Interest by Seller

The Seller, hereby declares and represents that, having made all reasonable enquiries, either:-

(a) none of the Seller and the Related Persons (as defined below) have any known actual, apparent, potential or perceived conflicts of interest that will, or might, arise in respect of the Standing Quotation, the Standing Quotation Submission, the provision of the Services or the performance of the obligations under the Contract (if awarded to the Seller); or

(b) the Seller has in this Declaration declared all such actual, apparent, potential or perceived conflicts to the Authority.

The Standing Quotation represents that, having made all reasonable enquiries, the following represents all of its actual, apparent, potential or perceived conflicts of interest in respect of the Standing Quotation, the Standing Quotation Submission, the provision of the Services or the performance of the obligations under the Contract (if awarded to the Seller):-

(List any conflict details or state "Nil Conflicts")

The Standing Quotation undertakes to advise the Authority in writing and keep the Authority advised of any actual, apparent, potential or perceived conflict of interest which the Seller or any Related Persons may have in respect of the Standing Quotation, the Standing Quotation Submission, the provision of the Services or the performance of the obligations under the Contract (if awarded to the Seller) (including all or any facts which may reasonably be considered to give rise to conflict of interest) immediately upon becoming aware of the same.

"Related Persons" means:-

(a) the directors, employees, agents and sub-contractors of the Seller (and if the Seller is a partnership, any of the members/partners of that partnership) who are or will be involved in the Standing Quotation, the Standing Quotation Submission, the provision of the Services or the performance of the obligations under the Contract (if awarded to the Seller); and

(b) any person or entity (i) which has control, directly or indirectly, over the Seller; (ii) which is controlled, directly or indirectly, by the Seller; or (iii) which is controlled by, or has controlled over, a person/entity referred to in paragraphs (i) or (ii). For the purposes of this Declaration, “control” means:

(aa) the possession by one person, directly or indirectly (through one or more intermediaries) of the power (whether holding office as director or otherwise) to affect, secure, direct and/or cause the direction of the management, affairs or policies of another person;

(bb) with respect to a corporation, partnership or other body corporate, such power in (aa) may be evidenced by (but is not limited to) that person: (i) holding shares or interests or possessing voting power in or in relation to that or any other person such as, but not limited to, the right to exercise, directly or indirectly, more than fifty percent (50%) of the other body corporate; and / or (ii) having powers conferred on that person by any constitution, memorandum or articles of association, partnership, agreement or arrangement (whether legally enforceable or not); and

(c) (i) any member of a partnership in which the Seller is a member or (ii) any company one or more of whose Directors is in common with one or more of the Directors of the Seller.

"Conflicts of interest" shall include (but are not limited to) (a) any situation where the personal, financial, commercial or other interest of the Seller or any of its Related Persons, conflict or compete, or may be expected to conflict or compete, with the Seller's duties to the Authority under the Contract; and (b) any situation where the Seller or any of its Related Persons may have any personal, financial, commercial or other interests in any potential service, advice, proposals or recommendations made or which may be made by the Seller under the Contract.

Signed by the Signatory for and on behalf of Seller:-

Name of Seller:	_____	Name and Title of Signatory:	_____
Tel:	_____	E-mail:	_____
Fax:	_____		
Date :	_____	Company Chop:	_____

Schedule H

General Specifications of Surgical Stapler for Endoscopic Surgery

M : Mandatory Requirement **D : Desirable Requirement** **O : Optional Requirement** The product offered shall incorporate the following components / requirements / features:	Bidders **MUST** indicate below the extent of compliance of the offered product(s) by filling in "**Yes**" or "**No**" and **provide the specifications of the offered product(s)** point by point against each clause of the Tender Specifications.

			Yes / No Provide details
			(Please indicate as appropriate)
1.	**General Requirements**		
1.1	The Stapler and Loading Units are designed for application in abdominal, gynecologic, pediatric and thoracic endoscopic surgery for resection, transaction and creation of anastomoses, and it shall comply with the following requirements. Bidders have been invited to make offers on any group of products.	M	
2.	**Group 1 -- Disposable Stapler (Straight)**		
2.1	The stapler shall consist of two, triple-staggered rows of titanium staples and simultaneously divides the tissue between the two, triple-staggered rows.	M	
2.2	The stapler shall be able to rotate 360 degrees.	M	
2.3	The stapler shall be reloadable for firing up to at least 8 times.	M	Max firing times per stapler: ____
2.4	The stapler shall be equipped with safety lock out mechanism, which will not fire the staples and cut tissue unless a particular button is pushed.	M	
2.5	A built-in safety device shall be available which helps to prevent the instrument from being closed or fired if the disposable loading units are not loaded properly.	M	
3.	**Group 2 -- Disposable Stapler (Articulating)**		
3.1	The stapler shall consist of two, triple-staggered rows of titanium staples and simultaneously divides the tissue between the two, triple-staggered rows.	M	
3.2	The stapler shall be able to rotate 360 degrees.	M	
3.3	The stapler shall be reloadable for firing up to at least 8 times.	M	Max firing times per stapler: ____
3.4	The stapler shall be equipped with safety lock out mechanism, which will not fire the staples and cut tissue unless a particular button is pushed.	M	
3.5	An articulation mechanism (in stapler or in loading unit) shall be available enabling the distal portion of the shaft to pivot to facilitate lateral access to the operative side.	M	

			Yes / No Provide details
			(Please indicate as appropriate)
3.6	The articulation angle shall be from 0 to at least 45 degrees.	M	
3.7	A built-in safety device shall be available which helps to prevent the instrument from being closed or fired if the disposable loading units are not loaded properly.	M	
4.	**Group 3 – Disposable/Reusable Stapler (Articulating, Powered-driven)**		
4.1	The stapler shall consist of two, triple-staggered rows of titanium staples and simultaneously divides the tissue between the two, triple-staggered rows.	M	
4.2	The stapler shall be able to rotate 360 degrees.	M	
4.3	The firing process shall be electrically operated with disposable or rechargeable batteries.	M	
4.4	The stapler shall be reloadable for firing up to at least 8 times with a new or fully-charged battery.	M	Max firing times per stapler: ____
4.5	The stapler shall be equipped with safety lock out mechanism, which will not fire the staples and cut tissue unless a particular button is pushed.	M	
4.6	An articulation mechanism (in stapler or in loading unit) shall be available enabling the distal portion of the shaft to pivot to facilitate lateral access to the operative side.	M	
4.7	The articulation angle shall be from 0 to at least 45 degrees.	M	
4.8	A built-in safety device shall be available which helps to prevent the instrument from being closed or fired if the disposable loading units are not loaded properly.	M	
4.9	It shall comply with the electrical safety requirements of IEC 60601-1 or equivalent.	M	
4.10	For reusable stapler, the warranty/ guarantee period shall be not less than 12 months from the acceptance of the stapler.	M	Warranty Period: ____ months Guarantee Period: ____ months
4.11	For reusable stapler, it shall be steam-sterilizable and autoclavable.	M	
5.	**Group 4 – Staple (Loading Unit)**		
5.1	The staple (loading unit) shall be fully compatible with the staplers offered in Group 1 to 3 above.	M	
5.2	The staples shall be made of titanium or titanium alloy.	M	
5.3	It can pass through 15mm trocars.	M	

			Yes / No Provide details
			(Please indicate as appropriate)
5.4	Bidder shall provide information of other available accessories with price breakdown, e.g. Stapler Line Reinforcement.	D	
6.	**Sterility (For Sterile Products)**		
6.1	The offered products shall be supplied sterile and do not contain any substance or chemical that is toxic, harmful or irritant to human being.	M	
7.	**Shelf Life (For Sterile Products)**		
7.1	Shelf Life of the offered products shall not be less than twenty-four (24) months upon receipt of goods by the receiving officer.	M	Shelf Life: ____ months
8.	**Packaging Requirement (For Sterile Products)**		
8.1	Item shall be supplied in sterile and individual pouch.	M	
8.2	The peelable pouch shall be manufactured from high wet-strength medical grade paper on one side and transparent film lamination on the other side with good peel performance enabling the content to be aseptically removed at the time of use.	M	
8.3	The distance between the end of a pouch and the nearest edge of the widthwise seal shall be sufficient to enable the two webs to be separated and peeled apart.	M	
8.4	It shall be sufficiently tensile on both sides to facilitate easy peeling-off and protection of the content.	M	
8.5	The individual package shall contain the entire item and be designed in such a way that the contents shall remain sterile and be protected against bacterial contamination.	M	
8.6	The package of individual item shall be free from foreign particle, free from dirt and impurity, and be sufficiently water repellent to prevent liquid or moisture from passing through.	M	
8.7	The multi-unit container (if any) and transport container shall provide sufficient protection to the offered products.	M	
8.8	Gross weight of the multi-unit / transport container when containing goods in full shall not exceed 14 kg.	M	Gross Weight:_____
8.9	**Marking of Unit Packaging** The unit container of each tendered item shall be marked with the following information:		
8.9.1	The manufacturer's name, trade mark or recognised symbol	M	
8.9.1	A texture description of the content	M	
8.9.3	Expiry date	M	
8.9.4	Batch/lot Number	M	.
8.9.5	Country of origin	D	
8.9.6	Indicate "Sterile"	M	

			Yes / No Provide details
			(Please indicate as appropriate)
8.9.7	Indicate "For single use"	M	
8.10	**Marking of Transportation Container** If there is multi-unit container in addition to the transportation container, the multi-unit container shall also be marked with the same information as the transportation container. The transportation container shall be marked with the following information :-		
8.10.1	The manufacturer's name, trade mark or recognized symbol	M	
8.10.2	A textual description of content	M	
8.10.3	Quantity of goods contained	M	
8.10.4	Batch/lot number	M	
8.10.5	Expiry date	M	
8.10.6	Indicate 'Sterile'	M	
8.10.7	Indicate 'For Single Use'	M	
8.10.8	Country of origin	M	
8.10.9	Recommended storage conditions	D	
8.10.10	Gross weight of carton	M	
9.	**Documentary** Tenderers shall submit with tender copies of 2 set (each set in separate file) of the following documentations for inspection and evaluation or otherwise offers will be considered incomplete and will be jeopardized. Manufacturer specified below refers to manufacturing facility/site of offered product.	M	
9.1	Certified true copy of Manufacturer's **Quality Assurance / Control Report (QCR)** of the Goods being offered. Tenderers are required to submit a QCR of the Goods manufactured in the most recent batch to serve as a sample of the report for inspection and evaluation. *(Note: Successful tenderer shall submit the QCR of goods to hospitals for inspection during delivery. A copy of the QCR of each batch of goods shall be submitted to PMMS, HAHO for record upon request.)*	M	
	For Sterile Products (Clauses 9.2 to 9.6)		
9.2	Certified true copy of valid certificate(s) issued by an independent and accredited certification institute to certify that the sterilization company is **qualified to conduct the sterilization** for the goods being offered and comply with ISO 11135 or ISO 11137 Standard (latest version) or equivalent	M	
9.3	Certified true copy of valid certificate(s) issued by independent and accredited certification institute to certify that the **packaging materials** of the offered product comply with ISO 11607 (latest version) or equivalent standard which are compatible for the sterilization process of the offered product.	M	

			Yes / No Provide details
			(Please indicate as appropriate)
	Alternatively, Documentary evidence issued by the supplier of packaging materials to certify that the packaging materials comply with the sterilization process of the offered product. Alternatively, Documentary evidence issued by independent and accredited certification institute to certify that the shelf life of the packaging materials of the offered product are equal to or longer than the shelf life of the offered product.		
9.4	Preferably, Tenderers shall submit certified true copy of the sterilization company's sterilization protocol for inspection and evaluation.	D	
9.5	Tenderers shall confirm in their tenders that sterilization company will be appointed to provide the sterilization services for the goods being offered throughout the Contract period. If the manufacturer possesses and maintains a qualified sterilization system to conduct the sterilization service for the goods being offered, Tenderers are also required to submit the same documentation proof as mentioned above for inspection and evaluation.	M	Type of Sterilization adopted: Appointed Sterilization Company:
9.6	Certified true copy of **Sterilization Report** of the goods manufactured in the most recent batch to serve as a sample of the report for inspection and evaluation. *(Note: Successful tenderer shall submit the Sterilization Report of goods to hospitals for inspection during delivery. A copy of the Sterilization Report of each batch of goods shall be submitted to PMMS, HAHO for record upon request.)*	M	
10.	**Logistics Support Services**		
10.1	Local Delivery (a) Provide delivery to specified hospitals on an "as and when required" basis. (b) Provide urgent delivery to hospitals at no additional charges:- - during office hours; - during non-office hours.	M	
10.2	Crisis Management and Contingency Back-up Tenderers shall provide a detailed contingency plan to show their capability in the back-up of the supply service to the Authority. (Please provide the contingency plan in details when lodging of tender.)	M	
11.	**Technical Supporting Services**		
11.1	Operational Training and On-site Support Tenderer is required to provide operational training to operators / users free of charge. The operational training	M	

			Yes / No Provide details
			(Please indicate as appropriate)
	shall be designed to enable the operators / users to use the Goods safely, effectively and properly in all aspects. (a) On-site briefing session/support shall be provided within 24 hours upon request. (b) Technical support shall be provided within 2 hours upon request during 8:00 am to 8:00 pm from Monday to Friday excluding public holidays.		
11.2	<u>Product Presentation</u> Bidder may be required to perform on-site briefing or demonstration as mentioned in Clauses 11.1 during the evaluation stage. Bidder shall be ready to attend such briefing / demonstration within 24 hours upon written notification through e-mail by HA. Bidder is required to bring samples of their offered products and equip with sufficient professional knowledge to demonstrate the product features to the satisfaction of HA.	M	

Notes for Seller

Instructions for Submission of Documentation

Sellers shall follow the following instructions to submit documentary evidence / certificates together with the quotation for inspection and evaluation. Failure to comply with, offers will be considered as incomplete and will be jeopardized.

1. All the documentary evidence / certifications must be submitted together with the quotation. Late submission may not be considered.

2. All the documentary evidence / certifications must be legitimately printed and certified true copy by manufacturer or Seller.

3. All the documentary evidence / certifications must be in English or Chinese language (except where technical information is expressly required to be provided in English). Where documentary evidence / certifications to be provided are in a language other than the English or Chinese language, a true, accurate and complete English or Chinese translation certified by the translator stating his/her relevant qualifications shall be provided with the original foreign-language document.

4. By completing the table in **Appendix I** (Page 67 of this Invitation to Quote), each submitted document must be indexed and corresponded clearly to the clause no. of the specifications for cross-reference. Failure to comply with this instruction which renders the misinterpretation of the submitted documents, if any, is solely the responsibility of Sellers.

Appendix I

Index Table for required Supporting Document

(Notes: Failure to comply with this instruction of quotation submission which renders the misinterpretation of the submitted documents, if any, is solely the responsibility of sellers.)

Clause No.	Description of Documents	For offered Item no.	Submitted or not (Yes / No)	Index on tenderer's offer
2.4 – Part I	Product information			
2.2(a)(i) – Part II	Manufacturer Licence			
2.2(a)(ii) – Part II	ISO 13485 of the manufacturer			
2.2(a)(iii) – Part II	CE Mark or / and FDA clearance for each offered product			
2.3 – Part II	Undertaking			
7 – Schedule B	Seller's Code of Conduct			
Schedule F	Product recall mechanism			
9.1 – Schedule H	Manufacturer's Quality Assurance / Control Report (QCR)			
9.2 – Schedule H	Certificate issued by an accredited certification institute to support that the sterilization company is qualified to conduct the sterilization			
9.3 – Schedule H	Latest version of medical device packaging standard ISO11607 or equivalent.			
9.4 – Schedule H	Sterilization company's sterilization protocol			
9.6 – Schedule H	Copy of Sterilization Report			

PART V
MEMORANDUM OF ACCEPTANCE

On behalf of the Hospital Authority, I .....……

(name and position of officer)

accept your offer upon the terms of this Contract so far as such offer relates to the following item(s) in the schedule:

.....

.....

.....

.....

.....

.....

Dated this ..... day of .....

Signed by the said.:	}	in the presence of :	}
.....……	}	.....…..…	}
.....……	}	.....……..	}
(name and designation of officer)	}	*(name and designation of* officer*)*	}

NOTICE FOR SUBMISSION OF STANDING QUOTATIONS

(Please read this notice before you provide any Personal Data to us)

The Hospital Authority (HA) is a statutory body which manages public hospitals. Our staff members may ask you to provide your Personal Data for purposes related to evaluation of your Standing Quotation.

If you wish to require access to and/or correction of your Personal Data, you may do so under Personal Data (Privacy) Ordinance. For request(s) relating to Hospital Authority Head Office, please contact the relevant Data Controller during office hours at:

Address: ***147B Argyle Street, Kowloon, Hong Kong***

REVIEW BODY ON BID CHALLENGES

This Standing Quotation is covered by the Agreement on Government Procurement of the World Trade Organisation ("WTO GPA") and the provisions of the WTO GPA will apply to this Standing Quotation. Sellers are requested to note that a Review Body on Bid Challenges (under WTO GPA) ("the Review Body") has been set up by the Government to deal with challenges made against alleged breaches of the WTO GPA and the relevant procedures for handling bid challenges are set out in the Rules of Operation of the Review Body ("the Rules") which are available for inspection at the Secretariat of the Review Body located at the Trade and Industry Department or which may be downloaded from the website http://www.info.gov.hk/reviewbody-gpa. In the event that a Seller believes that a breach of the WTO GPA has occurred, the Sellers may, within ten (10) working days after he/she knew or reasonably should have known the basis of the challenge, lodge a challenge to the Review Body on the alleged breaches of the WTO GPA. Nevertheless, the Seller is encouraged to seek resolution of its complaint in consultation with the Authority before lodging a complaint to the Review Body. In such instances, the Authority shall accord impartial and timely consideration to any such complaint, in a manner that is not prejudicial to obtaining corrective measures through the Review Body.

Sellers are also to note that the Review Body may receive and consider a late challenge, if satisfied that reasonable cause for the delay has been shown, but a challenge shall not be considered if it is filed later than thirty (30) days after the basis of the challenge is known or reasonably should have been known.