COCHLEAR IMPLANTS

Closing Date: 15 NOV 2011 at 10:00am CET

Date Published: 20 SEP 2011

CPV No.: 33185200-2

Cost of the Tender Document: €270.00

Proof of Purchase (Receipt of Purchase of tender document) is to be submitted with offer.

IMPORTANT:

• Tenderers are to ensure that the mandatory tender guarantee (bid bond) of €20,000 is to remain valid for a period of 180 days from closing date of tender, that is, up to 14 MAY 2012.

Clarifications shall be uploaded and will be available to view/download from www.contracts.gov.mt/tenders
# SUPPLIES TENDER

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A. GENERAL PART

1. General Instructions

1.1 In submitting a tender, the tenderer accepts in full and in its entirety, the content of this tender document, including subsequent Clarifications issued by the Central Government Authority, whatever his own corresponding conditions may be, which he hereby waives. Tenderers are expected to examine carefully and comply with all instructions, forms, contract provisions and specifications contained in this tender document.

No account can be taken of any reservation in the tender as regards the tender document; any disagreement, contradiction, alteration or deviation shall lead to the tender offer not being considered any further.

The Evaluation Committee shall, after having obtained approval by the General Contracts Committee, request rectifications in respect of incomplete/non-submitted information pertinent to the documentation as outlined in sub-Clause 16.1(a), 16.1(b), and 16.1(c) of these Instructions to Tenderers. Such rectification/s must be submitted within two (2) working days from notification, and will be subject to a non-refundable administrative penalty of €50: failure to comply shall result in the tender offer not being considered any further.

No rectification shall be allowed in respect of the documentation as outlined in sub-Clause 16.1(d), 16.1(e) and 16.1(f) of these Instructions to Tenderers. Only clarifications on the submitted information in respect of the latter may be eventually requested.

1.2 The subject of this tender is the supply of the following goods: Cochlear implants.

1.3 The place of acceptance of the supplies shall be Government Health Procurement Services, the time-limits for delivery shall be as indicated in Volume 3 - Technical Specifications, and the INCOTERM applicable shall be Delivery (Duty Paid).

1.4 This is a unit-price contract.

1.5 The tenderer will bear all costs associated with the preparation and submission of the tender. The Central Government Authority will in no case be responsible or liable for such costs, whatever the conduct or outcome of the procedure.

1.6 The Central Government Authority retains ownership of all tenders received under this tender procedure. Consequently, tenderers have no right to have their tenders returned to them.

2. Timetable

<table>
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<td>Clarification Meeting/Site Visit (Refer to Clause 9.1)</td>
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<td>16 days before deadline for submissions of tenders</td>
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<td>Last date on which additional information are issued by the Contracting Authority</td>
<td>6 days before deadline for submissions of tenders</td>
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<td>Deadline for submission of tenders / Tender Opening Session (unless otherwise modified in terms of Clause 11.3)</td>
<td>As per notice on Government Gazette</td>
<td>10:00am CET</td>
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* All times Central European Time (CET)
3. Lots

3.1 Government reserves the right to award the item/s requested to more than one contractor, unless otherwise specified in this tender document (Volume 3 - Technical Specifications).

4. Financing

4.1 The project is financed from local budget funds.

4.2 The beneficiary of the financing is Government Health Procurement Services.

5. Eligibility

5.1 Participation in tendering is open on equal terms to all natural and legal persons of the Member States of the European Union, the beneficiary country, any other country in accordance with Regulation 76 of the Public Procurement Regulations.

5.2 Natural persons, companies or undertakings who fall under any of the conditions set out in Regulation 50 of the Public Procurement Regulations, 2010 (Legal Notice 296 of 2010) may be excluded from participation in and the award of contracts. Tenderers or candidates who have been guilty of making false declarations will also incur financial penalties representing 10% of the total value of the contract being awarded.

5.3 All materials, equipment and services to be supplied under the contract must originate in an eligible country. For these purposes, "origin" means the place where the materials and/or equipment are mined, grown, produced or manufactured and/or from which services are provided.

6. Selection Criteria

6.1 In order to be considered eligible for the award of the contract, tenderers must provide evidence that they meet or exceed certain minimum qualification criteria described hereunder.

6.1.1 No evidence of economic and financial standing is required.

6.1.2 A certified true copy of the registration certificate as issued by the local regulatory authority (MRA) in relation of the medicinal product requested through the call for offers, signed by the Responsible Person of the tendering company is to be submitted with the tender document. (Applicable for Medicinal Products only)

6.1.3 Information about the tenderer's technical capacity.

This information must follow the form in Volume 1, Section 4 of the tender documents and includes:

- A list of principal deliveries effected during the last 2 years (Volume 1, Section 4).

In so listing the end clients, the tenderer is giving his consent to the Evaluation Committee, so that the latter may, if it deems necessary, contact the relevant clients, with a view to obtain from them an opinion on the works provided to them, by the tenderer. The Evaluation Committee reserves the right to request additional documentation in respect of the deliveries listed.

7. Only One Tender Per Tenderer

7.1 A company may not tender for a given contract both individually and as a partner in a joint venture/consortium.
7.2 A company may not tender for a given contract both individually/partner in a joint venture/consortium, and at the same time be nominated as a subcontractor by any other tenderer, or joint venture/consortium.

7.3 A company may act as a subcontractor for any number of tenderers, and joint ventures/consortia, provided that it does not participate individually or as part of a joint venture/consortium, and that the nominations do not lead to a conflict of interest, collusion, or improper practice.

8. Tender Expenses

8.1 The tenderer will bear all costs associated with the preparation and submission of the tender.

8.2 The Central Government Authority will neither be responsible for, nor cover, any expenses or losses incurred by the tenderer through site visits and inspections or any other aspect of his tender.

9. Clarification Meeting/Site Visit

9.1 No clarification meeting/site visit is planned.

B. TENDER DOCUMENTS

10. Content of Tender Document

10.1 The set of tender documents comprises the following documents and should be read in conjunction with any clarification notes issued in accordance with Clause 24:

Volume 1 Instructions to Tenderers
Volume 2 Draft Contract
  - General Conditions (available online from www.contracts.gov.mt/conditions)
  - Special Conditions
Volume 3 Technical Specifications and Technical Conditions
Volume 4 Financial Bid/Bill of Quantities
Volume 5 Drawings (if applicable)

10.2 Tenderers bear sole liability for examining with appropriate care the tender documents, including those design documents available for inspection, and any clarification notes to the tender documents issued during the tendering period, and for obtaining reliable information with respect to conditions and obligations that may in any way affect the amount or nature of the tender or the execution of the works. In the event that the tenderer is successful, no claim for alteration of the tender amount will be entertained on the grounds of errors or omissions in the obligations of the tenderer described above.

10.3 The tenderer must provide all documents required by the provisions of the tender document. All such documents, without exception, must comply strictly with these conditions and provisions and contain no alterations made by the tenderer.

11. Explanations/Clarification Notes Concerning Tender Documents

11.1 Tenderers may submit questions in writing to the Central Government Authority through:
  - sending an email to info.contracts@gov.mt
  - online from the Registered Users’ Questions and Answers facility within the tender’s page
  - through www.contracts.gov.mt/contact-us
  - fax number +356 21247681

up to 16 calendar days before the deadline for submission of tenders. The Central Government Authority must reply to all tenderers’ questions, and amend the tender documents by publishing clarification notes, up to at least 6 calendar days before the
TENDER PREVIEW

11.2 Questions and answers, and alterations to the tender document will be published as a clarification note on the website of the Department of Contracts (www.contracts.gov.mt/tenders) within the respective tender’s page, under the subheading “Preview & Free Tender Documents, and Clarifications”. Clarification notes will constitute an integral part of the tender documentation, and it is the responsibility of tenderers to visit this website and be aware of the latest information published online prior to submitting their Tender.

11.3 The Central Government Authority may, at its own discretion, as necessary and in accordance with Clause 24, extend the deadline for submission of tenders to give tenderers sufficient time to take clarification notes into account when preparing their tenders.

12. Labour Law

12.1 Particular attention is drawn to the conditions concerning the employment of labour in Malta and the obligation to comply with all regulations, rules or instructions concerning the conditions of employment of any class of employee.

13. Law

13.1 By submitting their tenders, tenderers are accepting that this procedure is regulated by Maltese Law, and are deemed to know all relevant laws, acts and regulations of Malta that may in any way affect or govern the operations and activities covered by the tender and the resulting contract.

C. TENDER PREPARATION

14. Language of Tenders

14.1 The tender and all correspondence and documents related to the tender exchanged by the tenderer and the Central Government Authority must be written in English.

14.2 Supporting documents and printed literature furnished by the tenderer must be in English / Maltese language.

15. Presentation of Tenders

15.1 Tenders must satisfy the following conditions:
(a) All tenders must be submitted in one original, clearly marked “original”, and one identical copy (including all documentation as in the original) signed in the same way as the original and clearly marked “copy”.
(b) Both documents are to be separately sealed and placed in another sealed envelope/package so that the bid can be identified as one tender submission. Following the tender opening session, the copy shall be kept, unopened, at the Department of Contracts, for verification purposes only should the need arise.
(c) All tenders must be received by date and time indicated in the timetable at Clause 2 and deposited in the tender box at the entrance of the Department of Contracts, Notre Dame Ravelin, Floriana, FRN 1600, Malta.
(d) All packages, as per (b) above, must bear only:
   (i) the above address;
   (ii) the reference of the invitation to tender concerned;
   (iii) the number of the lot(s) to which the tender refers (if applicable);
   (iv) the name of the tenderer.

16. Content of Tender

16.1 The tender must comprise the following duly completed documents, inserted in a single, sealed envelope (unless their volume requires a separate submission:...
(a) An original bid-bond for the amount of €20,000, in the form provided in Volume 1, Section 3(Note 1)

(b) General Administrative Information(Note 2)

(i) Proof of Purchase of tender document (receipt)
(ii) Statement on Conditions of Employment (Volume 1 Section 4, No. 1)

Selection Criteria

(c) Financial and Economic Standing(Note 2)

Not Applicable

(d) Technical Capacity(Note 3)

(i) Certified true copy of Registration Certificate (if applicable)
(ii) List of Principal Deliveries (Volume 1 Section 4, No. 2)

(e) Evaluation Criteria/Technical Specifications(Note 3)

(i) Tenderer’s Technical Offer in response to specifications (Volume 3)
(ii) Declaration Sheet (Volume 4, Section 2)
(iii) Literature/List of Samples (Volume 1, Section 4)

(f) Financial Offer/Bill of Quantities(Note 3)

(i) The Tender Form in accordance with the form provided in Volume 1, Section 2; a separate Tender Form is to be submitted for each option tendered, each form clearly marked ‘Option 1’, ‘Option 2’ etc.;
(ii) A financial bid calculated on a basis of Delivered Duty Paid (DDP) for the works/supplies tendered [inclusive of spare parts/after-sales services/maintenance/training as applicable] in the form provided in Volume 4.

Notes to Clause 16.1:

1. Tenderers will be requested to clarify/rectify, within two working days from notification, the tender guarantee only in the following two circumstances: either incorrect validity date, and/or incorrect value.

2. Tenderers will be requested to either clarify/rectify any incorrect and/or incomplete documentation, and/or submit any missing documents within two working days from notification.

3. No rectification shall be allowed. Only clarifications on the submitted information may be requested.

Tenderers must indicate where the above documentation is to be found in their offer by using an index. All documentation is to be securely bound/filed.

Tenderers are NOT required NOR expected to submit, with their offer, any components of the tender document except those specifically mentioned in Clause 16.

17. Tender Prices

17.1 Tenderers will be deemed to have satisfied themselves, before submitting their tender, to its correctness and completeness, to have taken account of all that is required for the full and proper performance of the contract, and to have included all costs in their rates and prices.

17.2 The tender must be submitted in Euro (€).

17.3 Tenderers must quote all components of the price inclusive of taxes, customs and import duties, and any discounts. Except as may otherwise be provided for in the contract, no payment will be made for items which have not been costed.
17.4 Different options are to be clearly identifiable in the technical and financial submission; a separate Tender Form (as per Volume 1, Section 2) marked ‘Option 1’, ‘Option 2’ etc. for each individual option clearly outlining the price of the relative option is to be submitted.

17.5 If the tenderer offers a discount, the discount must be absorbed in the rates of the Bill of Quantities/Financial Statement.

17.6 The prices for the contract must include all of the works to be provided. The prices quoted are fixed and not subject to revision or escalation in costs, unless otherwise provided for in the Special Conditions.

18. **Currencies of Tender and Payments**

18.1 The currency of the tender is the Euro (€). All sums in the breakdown of the overall price, in the questionnaire and in other documents must be expressed in Euro (€).

18.2 Payments will be made upon certification of supplies by the Contracting Authority, based on the invoice issued by the Contractor, in accordance with the timeframes, terms and conditions of the contract.

18.3 All correspondence relating to payments, including invoices and interim and final statements must be submitted as outlined in the contract.

19. **Period ofValidity of Tenders**

19.1 Tenders must remain valid for a period of 180 days after the deadline for submission of tenders indicated in the contract notice, the tender document or as modified in accordance with Clauses 11.3 and/or 24. Any tenderer who quotes a shorter validity period will be rejected.

19.2 In exceptional circumstances the Central Government Authority may request that tenderers extend the validity of tenders for a specific period. Such requests and the responses to them must be made in writing. A tenderer may refuse to comply with such a request without forfeiting his tender guarantee (Bid Bond). However, his tender will no longer be considered for award. If the tenderer decides to accede to the extension, he may not modify his tender. He is, however, bound to extend the validity of his tender guarantee for the revised period of validity of the tender.

19.3 The successful tenderer must maintain his tender for a further 60 days from the date of notification of award.

20. **Tender Guarantee (Bid Bond)**

20.1 The tender guarantee is set at € 20,000 (twenty thousand Euro) and must be an original and valid guarantee presented in the form specified in Section 3. The guarantee must be issued by a local Maltese Bank or a Financial Institution licensed by a recognized Financial Regulator in the country where the company is located and who assumes responsibility for claims and payments to the amount as stated above. It must remain valid for a period of 180 days from closing date of tender. The tender guarantee must be drawn up in the name of the Director General of the Department of Contracts, Notre Dame Ravelin, Floriana, FRN 1600, Malta.

The tender guarantee (bid bond) is intended as a pledge that the tenderer will not retract his offer up to the expiry date of the guarantee and, if successful, that he will enter into a contract with the Director General of Contracts on the terms and conditions stated in the tender document.

Hence, the guarantee shall be forfeited if the tenderer withdraws his tender before the above-mentioned validity date or if the tenderer fails to provide the Performance Guarantee.
Tender guarantees provided by tenderers who have not been selected shall be released within 30 calendar days from the signing of the contract. The tender guarantee of the successful tenderer shall be released on the signing of the contract, and on submission of a valid performance guarantee.

Offers that are not accompanied with the mandatory Tender Guarantee (Bid Bond) by the Closing Date and Time of the tender will be automatically disqualified.

Tenderers will be requested to clarify/rectify, within two working days from notification, the tender guarantee submitted, only in the following two circumstances: either incorrect validity date, and/or incorrect value. Such rectification/s must be submitted within two (2) working days, and will be subject to a non-refundable administrative penalty of €50. Failure to comply shall result in the tender offer not being considered any further.

21. Variant Solutions

21.1 No variant solutions will be accepted. Tenderers must submit a tender in accordance with the requirements of the tender document.

22. Preparation and Signing of Tenders

22.1 All tenders must be submitted in one original, clearly marked “original”, and one identical copy (including all documentation as in the original) signed in the same way as the original and clearly marked “copy”. Tenders must comprise the documents specified in Clause 16 above.

It is the responsibility of the tenderers to ensure that both the original and the copy are an identical representation of one another.

22.2 The tenderer’s submission must be typed in, or handwritten in indelible ink. Any pages on which entries or corrections to his submission have been made must be initialled by the person or persons signing the tender. All pages must be numbered consecutively by hand, machine or in any other way acceptable to the Central Government Authority.

22.3 The tender must contain no changes or alterations, other than those made in accordance with instructions issued by the Central Government Authority (issued as clarification notes) or necessitated by errors on the part of the tenderer. In the latter case, corrections must be initialled by the person signing the tender.

22.4 The tender will be rejected if it contains any alteration, tampering, addition or deletion to the tender documents not specified in a clarification note issued by the Central Government Authority.

D. SUBMISSION OF TENDERS

23. Sealing and Marking of Tenders

23.1 The tenders must be submitted in English and deposited in the Department’s tender box before the deadline specified in Clause 2 or as otherwise specified in accordance with Clause 11.1 and/or 24.1. They must be submitted:

EITHER by recorded delivery (official postal/courier service) or hand delivered to:

Department of Contracts,
Notre Dame Ravelin,
Floriana, FRN 1600
Malta

Tenders submitted by any other means will not be considered.

23.2 Tenderers must seal the original and the copy of their tender as outlined in Clause 15.

23.3 If the outer envelope is not sealed and marked as required in Sub clause 15.1, the Central Government Authority will assume no responsibility for the misplacement or
24. Extension of Deadline for Submission of Tenders

24.1 The Central Government Authority may, at its own discretion, extend the deadline for submission of tenders by issuing a clarification note in accordance with Clause 11. In such cases, all rights and obligations of the Central Government Authority and the tenderer regarding the original date specified in the contract notice will be subject to the new date.

25. Late Tenders

25.1 All tenders received after the deadline for submission specified in the contract notice or these instructions will be kept by the Central Government Authority. The associated guarantees will be returned to the tenderers.

25.2 No liability can be accepted for late delivery of tenders. Late tenders will be rejected and will not be evaluated.

26. Alterations and Withdrawal of Tenders

26.1 Tenderers may alter or withdraw their tenders by written notification prior to the deadline for submission of tenders. No tender may be altered after the deadline for submission.

26.2 Any notification of alteration or withdrawal must be prepared, sealed, marked and submitted in accordance with Clause 23, and the envelope must also be marked with "alteration" or "withdrawal".

26.3 The withdrawal of a tender in the period between the deadline for submission and the date of expiry of the validity of the tender will result in forfeiture of the tender guarantee provided for in Clause 20.

E. OPENING AND EVALUATION OF OFFERS

27. Opening of Tenders

27.1 Tenders will be opened in public session on the date and time indicated in the timetable at Clause 2 (or as otherwise specified in accordance with Clause 11.1 and/or 24.1) at the Department of Contracts, Notre Dame Ravelin, Floriana, FRN 1600, Malta by the General Contracts Committee. They will draw up a ‘Summary of Tenders Received’ which will be published on the notice board at the Department of Contracts and shall also be available to view on the Department’s website, www.contracts.gov.mt/tenders.

27.2 At the tender opening, the tenderers' names, the tender prices, variants, written notification of alterations and withdrawals, the presence of the requisite tender guarantee and any other information the Central Government Authority may consider appropriate will be published.

27.3 Envelopes marked "withdrawal" will be read out first and returned to the tenderer.

27.4 Reductions or alterations to tender prices made by tenderers after submission will not be taken into consideration during the analysis and evaluation of tenders.

28. Secrecy of the Procedure

28.1 After the opening of the tenders, no information about the examination, clarification, evaluation or comparison of tenders or decisions about the contract award may be disclosed before the notification of award.

28.2 Information concerning checking, explanation, opinions and comparison of tenders and
recommendations concerning the award of contract, may not be disclosed to tenderers or any other person not officially involved in the process unless otherwise permitted or required by law.

28.3 Any attempt by a tenderer to approach any member of the Evaluation Committee/Central Government Authority directly during the evaluation period will be considered legitimate grounds for disqualifying his tender.

29. Clarification of Tenders

29.1 When checking and comparing tenders, the evaluation committee may, after obtaining approval from the General Contracts Committee, ask a tenderer to clarify any aspect of his tender.

29.2 Such requests and the responses to them must be made by e-mail or fax. They may in no circumstances alter or try to change the price or content of the tender, except to correct arithmetical errors discovered by the evaluation committee when analysing tenders, in accordance with Clause 31.

30. Tender Evaluation Process

30.1 The following should be read in conjunction with Clause 27.

30.2 Part 1: Administrative Compliance

The Evaluation Committee will check the compliance of tenders with the instructions given in the tender document, and in particular the documentation submitted in respect of Clause 16.

The Evaluation Committee shall, after having obtained approval by the General Contracts Committee, request rectifications in respect of incomplete/non-submitted information pertinent to the documentation as outlined in sub-Clause 16.1(a), and 16.1(b) of these Instructions to Tenderers. Such rectification/s must be submitted within two (2) working days from notification, and will be subject to a non-refundable administrative penalty of €50: failure to comply shall result in the tender offer not being considered any further. No rectification shall be allowed in respect of the documentation as outlined in sub-Clause 16.1(c), 16.1(d), and 16.1(e) of these Instructions to Tenderers. Only clarifications on the submitted information in respect of the latter may be eventually requested.

30.3 Part 2: Eligibility and Selection Compliance

Tenders which have been considered administratively compliant shall be evaluated for admissibility as outlined below:

(i) Eligibility Criteria

- Tender Form (Volume 1, Section 2)

(ii) Selection Criteria

- Evidence of financial and economic standing (sub-Clause 6.1.1) - Three-package tenders only.
- Certified true copy of Registration Certificate (in case of medicinal product) (sub-Clause 6.1.2)
- Evidence of technical capacity (sub-Clause 6.1.3)

30.4 Part 3: Technical Compliance

At this step of the evaluation process, the Evaluation Committee will analyse the administratively-compliant tenders’ technical conformity in relation to the technical specifications (Volume 3, and the documentation requested by the Contracting Authority as per sub-Clause 16(e)), classifying them technically compliant or non-compliant.
Tenders who are deemed to be provisionally technically compliant through the evaluation of their technical offer (especially the specifications) shall be requested to submit samples so that the Evaluation Committee will corroborate the technical compliance of the offers received.

In the case of suppliers who are already supplying the product being offered, the tenderer may be exempted from submitting samples. However the specific brand name and the respective reference of the Letter of Acceptance/Contract must be clearly indicated in the tender submission.

30.5 Part 4. Financial Evaluation

The financial offers for tenders which were not eliminated during the technical evaluation (i.e., those found to be technically compliant) will be evaluated.

The Evaluation Committee will check that the financial offers contain no arithmetical errors as outlined in Clause 31. [If the tender procedure contains several lots, financial offers are compared for each lot.] The financial evaluation will have to identify the best financial offer [for each lot].

31. Correction of Arithmetical Errors

31.1 Admissible tenders will be checked for arithmetical errors by the Evaluation Committee. Errors will be corrected as follows:
   (a) where there is a discrepancy between amounts in figures and in words, the amount in words will prevail;
   (b) where there is a discrepancy between a unit price and the total amount derived from the multiplication of the unit price and the quantity, the unit price as quoted will prevail.

31.2 The amount stated in the tender will be adjusted by the Evaluation Committee in the event of error, and the tenderer will be bound by that adjusted amount. In this regard, the Evaluation Committee shall seek the prior approval of the General Contracts Committee to communicate the revised price to the tenderer. If the tenderer does not accept the adjustment, his tender will be rejected and his tender guarantee forfeited.

31.3 When analysing the tender, the evaluation committee will determine the final tender price after adjusting it on the basis of Clause 31.1.

F. CONTRACT AWARD

32. Criteria for Award

32.1 The sole award criterion will be the price. The contract will be awarded to the cheapest priced tender satisfying the administrative and technical criteria.

33. Right Of The Central Government Authority To Accept Or Reject Any Tender

33.1 The Central Government Authority reserves the right to accept or reject any tender and/or to cancel the whole tender procedure and reject all tenders. The Central Government Authority reserves the right to initiate a new invitation to tender.

33.2 In the event of a tender procedure's cancellation, tenderers will be notified by the Central Government Authority. If the tender procedure is cancelled before the outer envelope of any tender has been opened, the sealed envelopes will be returned, unopened, to the tenderers.

33.3 Cancellation may occur where:
   (a) the tender procedure has been unsuccessful, namely where no qualitatively or financially worthwhile tender has been received or there has been no response at all;
   (b) the economic or technical parameters of the project have been fundamentally altered;
(c) exceptional circumstances or force majeure render normal performance of the project impossible;
(d) all technically compliant tenders exceed the financial resources available;
(e) there have been irregularities in the procedure, in particular where these have prevented fair competition.

In no circumstances will the Central Government Authority be liable for damages, whatever their nature (in particular damages for loss of profits) or relationship to the cancellation of a tender, even if the Central Government Authority has been advised of the possibility of damages. The publication of a contract notice does not commit the Central Government Authority to implement the programme or project announced.

34. Notification of Award, Contract Clarifications

34.1 Prior to the expiration of the period of validity of tenders, the Central Government Authority will notify the successful tenderer, in writing, that his tender has been recommended for award by the General Contracts Committee, pending any appeal being lodged in terms of Part XIII of the Public Procurement Regulations (being reproduced in Volume 1, Section 6).

34.2 Unsuccessful bidders shall be notified with the outcome of the evaluation process, and will be provided the following information:
(i) the criteria for award;
(ii) the name of the successful tenderer;
(iii) the recommended price of the successful bidder;
(iv) the reasons why the tenderer did not meet the technical specifications/ notification that the offer was not the cheapest (if applicable);
(v) the deadline for filing a notice of objection (appeal);
(vi) the deposit required if lodging an appeal.

34.3 The recommendations of the General Contracts Committee shall be published on the Notice Board of the Department of Contracts, and published online on the Department’s website, www.contracts.gov.mt/gcc.

35. Contract Signing and Performance Guarantee

35.1 After the lapse of the appeals period, and pending that no objections have been received and/or upheld, the successful tenderer may be invited to clarify certain contractual questions raised therein. Such clarification will be confined to issues that had no direct bearing on the choice of the successful tender. The outcome of any such clarifications will be set out in a Memorandum of Understanding, to be signed by both parties and incorporated into the contract.

35.2 Within 15 calendar days of receiving the contract (against acknowledgment of receipt) from the Central Government Authority, the successful tenderer will sign and date the contract and return it to the Central Government Authority with the performance guarantee and the Financial Identification Form (if applicable). On signing of the contract by the Central Government Authority, the successful tenderer will become the Contractor and the contract will enter into force.

35.3 Before the Central Government Authority signs the contract with the successful tenderer, the successful tenderer may be requested to provide the documentary proof or statements required to show that it does not fall into any of the exclusion situations listed in Clause 7 of the Tender Form (Volume 1, Section 2). The above mentioned documents must be submitted by every member of a Joint Venture/Consortium (if applicable).

35.4 If the selected tenderer fails to sign and return the contract, other required documentation, and any guarantees required within the prescribed 15 calendar days, the Central Government Authority may consider the acceptance of the tender to be cancelled without prejudice to the Central Government Authority’s right to seize the guarantee, claim compensation or pursue any other remedy in respect of such failure, and the successful tenderer will have no claim whatsoever on the Central Government Authority.
The tenderer whose tender has been evaluated as [second cheapest acceptable] may be recommended for award, and so on and so forth.

35.5 Only the signed contract will constitute an official commitment on the part of the Central Government Authority, and activities may not begin until the contract has been signed by the Central Government Authority and the successful tenderer.

35.6 Tender guarantees (bid bonds) provided by tenderers who have not been selected shall be released within 30 calendar days from the signing of the contract. The tender guarantee of the successful tenderer shall be released on the signing of the contract, and on submission of a valid performance guarantee.

35.7 The performance guarantee referred to in the General Conditions is set at 10% of the amount of the contract and must be presented in the form specified in Volume 2, Section 4, to the tender document the performance guarantee shall be released within 30 days of the signing of the Final Statement of Account (Final Bill), unless the Special Conditions provide otherwise.

36. Period of Delivery

36.1 The period of delivery indicated in Volume 3 - Technical Specifications, commences from date of Confirmation of Order.

36.2 The Contractor must inform the Central Government Authority's representative by return that he has received the notice.

G. MISCELLANEOUS

37. Ethics Clauses

37.1 Any attempt by a candidate or tenderer to obtain confidential information, enter into unlawful agreements with competitors or influence the committee or the Central Government Authority during the process of examining, clarifying, evaluating and comparing tenders will lead to the rejection of his candidacy or tender and may result in administrative penalties.

37.2 Without the Central Government Authority's prior written authorisation, the Contractor and his staff or any other company with which the Contractor is associated or linked may not, even on an ancillary or subcontracting basis, supply other services, carry out works or supply equipment for the project. This prohibition also applies to any other programmes or projects that could, owing to the nature of the contract, give rise to a conflict of interest on the part of the Contractor.

37.3 When putting forward a candidacy or tender, the candidate or tenderer must declare that he is affected by no potential conflict of interest, and that he has no particular link with other tenderers or parties involved in the project.

37.4 The Contractor must at all times act impartially and as a faithful adviser in accordance with the code of conduct of his profession. He must refrain from making public statements about the project or services without the Contracting Authority's prior approval. He may not commit the Contracting Authority in any way without its prior written consent.

37.5 For the duration of the contract, the Contractor and his staff must respect human rights and undertake not to offend the political, cultural and religious morals of Malta.

37.6 The Contractor may accept no payment connected with the contract other than that provided for therein. The Contractor and his staff must not exercise any activity or receive any advantage inconsistent with their obligations to the Contracting Authority.

37.7 The Contractor and his staff are obliged to maintain professional secrecy for the entire duration of the contract and after its completion. All reports and documents drawn up or received by the Contractor are confidential.
37.8 The contract governs the Parties’ use of all reports and documents drawn up, received or presented by them during the execution of the contract.

37.9 The Contractor shall refrain from any relationship likely to compromise his independence or that of his staff. If the Contractor ceases to be independent, the Central Government Authority may, regardless of injury, terminate the contract without further notice and without the Contractor having any claim to compensation.

37.10 The tender(s) concerned will be rejected or the contract terminated if it emerges that the award or execution of a contract has given rise to unusual commercial expenses. Such unusual commercial expenses are commissions not mentioned in the main contract or not stemming from a properly concluded contract referring to the main contract, commissions not paid in return for any actual and legitimate service, commissions remitted to a tax haven, commissions paid to a recipient who is not clearly identified or commissions paid to a company which has every appearance of being a front company.

38. Data Protection and Freedom of Information

38.1 Any personal data submitted in the framework of the procurement procedure and/or subsequently included in the contract shall be processed pursuant to the Data Protection Act (2001). It shall be processed solely for the purposes of the performance, management and follow-up of the procurement procedure and/or subsequent contract by the Central Government Authority/Contracting Authority without prejudice to possible transmission to the bodies charged with a monitoring or inspection task in conformity with National and/or Community law.

38.2 The provisions of this contract are without prejudice to the obligations of the Central Government Authority in terms of the Freedom of Information Act (Cap. 496 of the Laws of Malta). The Central Government Authority, prior to disclosure of any information to a third party in relations to any provisions of this contract which have not yet been made public, shall consult the contractor in accordance with the provisions of the said Act, pertinent subsidiary legislation and the Code of Practice issued pursuant to the Act. Such consultation shall in no way prejudice the obligations of the Central Government Authority in terms of the Act.

39. Gender Equality

39.1 In carrying out his/her obligations in pursuance of this contract, the tenderer shall ensure the application of the principle of gender equality and shall thus ‘inter alia’ refrain from discriminating on the grounds of gender, marital status or family responsibilities. Tenderers are to ensure that these principles are manifest in the organigram of the company where the principles aforementioned, including the selection criteria for access to all jobs or posts, at all levels of the occupation hierarchy are amply proven. In this document words importing one gender shall also include the other gender.
VOLUME 1 SECTION 2 - TENDER FORM

(A separate, distinct Tender Form must be submitted for EACH OPTION - if applicable - submitted)

Publication reference: ..................................................
<Name of Tender> <File Reference Number>

A  TENDER SUBMITTED BY

<table>
<thead>
<tr>
<th>Name(s) of tenderer(s)</th>
<th>Nationality</th>
<th>Proportion of Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leader</td>
<td></td>
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<tr>
<td>Partner</td>
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<tr>
<td>Etc ...</td>
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<td></td>
</tr>
</tbody>
</table>

B  CONTACT PERSON (for this tender)

<table>
<thead>
<tr>
<th>Name</th>
<th>Surname</th>
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<table>
<thead>
<tr>
<th>Telephone</th>
<th>Fax</th>
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<td>(___) ______________</td>
<td>(___) ______________</td>
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<th>Address</th>
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<th>E-mail</th>
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</table>
**C TENDERER’S DECLARATION(S)**

To be completed and signed by the tenderer (including each partner in a consortium).

In response to your letter of invitation to tender for the above contract, we, the undersigned, hereby declare that:

1. We have examined, and accept in full and in its entirety, the content of this tender document (including any subsequent Clarifications Notes issued by the Central Government Authority) for invitation to tender No ________/_______ of _______/______/_____. We hereby accept the contents thereto in their entirety, without reservation or restriction. We also understand that any disagreement, contradiction, alteration or deviation shall lead to our tender offer not being considered any further.

2. We offer to execute, in accordance with the terms of the tender document and the conditions and time limits laid down, without reserve or restriction, the supplies of the following item/s:

   Cochlear implants.

3. The unit/total price of our tender, delivered to stores as directed (inclusive of duties, VAT, other taxes and any discounts) is:

<table>
<thead>
<tr>
<th>Item</th>
<th>Unit Price for 36 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a. Cochlear implants bilateral</td>
<td>Euro</td>
</tr>
<tr>
<td>1b. Cochlear implants unilateral</td>
<td></td>
</tr>
</tbody>
</table>

   * Applicable as indicated on Contract Agreement.

4. This tender is valid for a period of 180 days from the final date for submission of tenders.

5. If our tender is accepted, we undertake to provide a performance guarantee of 10% of the contract value as required by the General Conditions.

6. We are making this application in our own right and for this tender. We confirm that we are not tendering for the same contract in any other form.

7. We are not bankrupt or under an administration appointed by the Court, or under proceedings leading to a declaration of bankruptcy. We also declare that we have not been convicted criminally, or found guilty of professional misconduct. Furthermore, we are up-to-date in the payment of social security contributions and other taxes.

8. We accept that we shall be excluded from participation in the award of this tender if compliance certificates in respect of declarations made under Clause 7 of this declaration are not submitted if and when required by the indicated dates.

9. We agree to abide by the ethics clauses of the instructions to tenderers and, in particular, have no potential conflict of interests or any relation with other candidates or other parties in the tender procedure at the time of the submission of this application. We have no interest of any nature whatsoever in any other tender in this procedure. We recognise that our tender may be excluded if we propose key experts who have been involved in preparing this project or engage such personnel as advisers in the preparation of our tender.
We will inform the Central Government Authority immediately if there is any change in the above circumstances at any stage during the implementation of the contract. We also fully recognise and accept that any false, inaccurate or incomplete information deliberately provided in this application may result in our exclusion from this and other contracts funded by the Government of Malta and the European Communities.

Our tender submission has been made in conformity with the Instructions to Tenderers, and in this respect we confirm having included in the appropriate packages as required, the following documentation:

(a) **Tender Guarantee** *(Note 1)*
   - Bid Bond

(b) **General Administrative Information** *(Note 2)*
   - Statement on Conditions of Employment (Volume 1 Section 4, No. 1)
   - Proof of Purchase of tender document (Receipt)

(c) **Selection Criteria** *(Note 2)*

(d) **Technical Capacity** *(Note 3)*
   - Certified true copy of Registration Certificate (if applicable)
   - List of Principal Deliveries (Volume 1 Section 4, No. 2)

(e) **Evaluation Criteria/Technical Specifications** *(Note 3)*
   - Tenderer’s Technical Offer
   - Declaration Sheet
   - Literature/List of Samples (Volume 1, Section 4)

(f) **Tender Form, and Financial Offer/Bill of Quantities** *(Note 3)*

**Notes:**

1. Tenderers will be requested to clarify/rectify, within two working days from notification, the tender guarantee only in the following two circumstances: either incorrect validity date, and/or incorrect value. This is indicated by the symbol ○.
2. Tenderers will be requested to either clarify/rectify any incorrect and/or incomplete documentation, and/or submit any missing documents within two working days from notification. This is indicated by the symbol ○.
3. No rectification shall be allowed. Only clarifications on the submitted information may be requested. This is indicated by the symbol ●.

I acknowledge that the Central Government Authority and/or Contracting Authority shall request rectifications in respect of incomplete/non-submitted information pertinent to the documentation listed in Clause 11(a), 11(b), and 11(c) of this Tender Form. We understand that such rectification/s must be submitted within two (2) working days, and will be subject to a non-refundable administrative penalty of €50, and that failure to comply shall result in our offer not being considered any further.

We note that the Central Government Authority is not bound to proceed with this invitation to tender and that it reserves the right to cancel or award only part of the contract. It will incur no liability towards us should it do so.

I/We confirm that if our offer is awarded, the stipulated Bank Guarantee is presented, using the wording of the specimen as at Volume 2 Section 4.

Name and Surname: ________________________________

I.D. / Passport Number: ____________________________

Signature of tenderer: ________________________________
Duly authorised to sign this tender on behalf of: ________________________________

Company/Lead Partner VAT No: ________________________________
(if applicable)

Stamp of the firm/company: ________________________________

Place and date: ________________________________
VOLUME 1 SECTION 3 - TENDER GUARANTEE FORM

[On the headed notepaper of the financial institutions providing the guarantee]

Whereas the Director of Contracts has invited tenders for

.....................................................................................................................................

and whereas Messrs .................................................................................................... [Name of tenderer]

(hereinafter referred to as the Tenderer) is submitting such a tender in accordance with such invitation, we

.................................................................................................. [Name of Bank], hereby guarantee to pay you on your first demand

in writing a maximum sum of twenty thousand Euro (€ 20,000) in case the Tenderer withdraws his tender

before the expiry date or in the case the Tenderer fails to provide the Performance Bond, if called upon to
do so in accordance with the Conditions of Contract.

The guarantee becomes payable on your first demand and it shall not be incumbent upon us to verify

whether such demand is justified.

This guarantee is valid for a period of one hundred and eighty (180) days from the closing date of submission

of tenders, and expires on the .............................................. Unless it is extended by us or returned to us for
cancellation before that date, any demand made by you for payment must be received at this office in
writing not later than the above-mentioned expiry date.

This document should be returned to us for cancellation or utilisation or expiry or in the event of the
guarantee being no longer required.

After the expiry date and in the absence of a written demand being received by us before such expiry date,
this guarantee shall be null and void, whether returned to us for cancellation or not, and our liability
hereunder shall terminate.

Yours faithfully,

..............................................................

Bank Manager

..............................................................

Date
1 - Statement on Conditions of Employment

It is hereby declared that all employees engaged on this contract shall enjoy working conditions such as wages, salaries, vacation and sick leave, maternity and parental leave as provided for in the relative Employment Legislation. Furthermore, we shall comply with Chapter 424 of the Laws of Malta (Occupational Health and Safety Authority Act) as well as any other national legislation, regulations, standards and/or codes of practice or any amendment thereto in effect during the execution of the contract.

In the event that it is proved otherwise during the execution of the contract it is hereby being consented that the contract is terminated with immediate effect and that no claim for damages or compensation be raised by us.

Signature: .............................................................
(the person or persons authorised to sign on behalf of the tenderer)

Date: .............................................................
2 - List of Principal Deliveries

List of principal deliveries effected during the past 2 years:

<table>
<thead>
<tr>
<th>Description of Supplies</th>
<th>Total Value of Supplies</th>
<th>Date of Delivery</th>
<th>Client*/Contracting Authority*</th>
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* In so listing the end clients, I am giving my consent to the Evaluation Committee, so that the latter may, if it deems necessary, contact the relevant clients, with a view to obtain from them an opinion on the supplies provided to them.

Signature: .................................................................

*(the person or persons authorised to sign on behalf of the tenderer)*

Date: ...........................................................................
3 - Literature/List of Samples in respect of item being offered

1. Literature to be submitted with the tender:

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>As requested in the tender document.</td>
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<td>1.2</td>
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<td>1.3</td>
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<td>1.8</td>
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<td>1.9</td>
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</tbody>
</table>

2. List of samples to be submitted within 2 days of being notified to do so:

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>Nil</td>
</tr>
<tr>
<td>2.2</td>
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<td>2.3</td>
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<td>2.9</td>
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</table>

Signature: ..................................................................................

(the person or persons authorised to sign on behalf of the tenderer)

Date: ...........................................................................................
VOLUME 1 SECTION 5 - GLOSSARY

Definitions

Note: the present definitions are given here for convenience only, in the context of the tender procedure. The definitions set out in the contract as concluded are determining for the relations between the parties to the contract.

Administrative order: Any instruction or order issued by the Project Manager to the Contractor in writing regarding the execution of the contract.

Breakdown of the overall price: A heading-by-heading list of the rates and costs making up the price for a lump-sum contract.

Central Government Authority: means the Department of Contracts

Contracting Authority: means the final beneficiary.

Conflict of interest: Any event influencing the capacity of a candidate, tenderer or supplier to give an objective and impartial professional opinion, or preventing him, at any moment, from giving priority to the interests of the Central Government Authority and the Contracting Authority. Any consideration relating to possible contracts in the future or conflict with other commitments, past or present, of a candidate, tenderer or supplier, or any conflict with his own interests. These restrictions also apply to subcontractors and employees of the candidate, tenderer or supplier.

Contract value: The total value of the contract to be paid by the Contracting Authority in terms of the agreed terms and conditions.

Contractor: The successful tenderer, once all parties have signed the contract.

Day: Calendar day.

Dayworks: Varied work inputs subject to payment on an hourly basis for the Contractor's employees and plant.

Defects Notification Period: The period stated in the contract immediately following the date of provisional acceptance, during which the Contractor is required to complete the works and to remedy defects or faults as instructed by the Engineer.

Drawings: Drawings provided by the Contracting Authority and/or the Engineer, and/or drawings provided by the Contractor and approved by the Engineer, for the carrying out of the works.

Engineer’s representative: Any natural or legal person, designated by the Engineer as such under the contract, and empowered to represent the Engineer in the performance of his functions, and in exercising such rights and/or powers as have been delegated to him. In this case, references to the Engineer will include his representative.

Equipment: Machinery, apparatus, components and any other articles intended for use in the works.

Evaluation Committee: a committee made up of an odd number of voting members (at least three) appointed by the Central Government Authority and possessing the technical, linguistic and administrative capacities necessary to give an informed opinion on tenders.

Final acceptance certificate: Certificate(s) issued by the Engineer to the Contractor at the end of the defects notification period stating that the Contractor has completed his obligations to construct, complete, and maintain the works concerned.

Final Beneficiary: The Department/Entity or other government body on whose behalf the Department of Contracts has issued this tender.

Foreign currency: Any currency permissible under the applicable provisions and regulations other than the Euro, which has been indicated in the tender.
**General conditions**: The general contractual provisions setting out the administrative, financial, legal and technical clauses governing the execution of contracts.

**General damages**: The sum not stated beforehand in the contract, which is awarded by a court or an arbitration tribunal, or agreed between the parties, as compensation payable to an injured party for a breach of the contract by the other party.

**In writing**: This includes any hand-written, typed or printed communication, including fax transmissions and electronic mail (e-mail).

**Liquidated damages**: The sum stated in the contract as compensation payable by the Contractor to the Contracting Authority for failure to complete the contract or part thereof within the periods under the contract, or as payable by either party to the other for any specific breach identified in the contract.

**Modification**: An instruction given by the Engineer which modifies the works.

**National currency**: The currency of the country of the Contracting Authority.

**Period**: A period begins the day after the act or event chosen as its starting point. Where the last day of a period is not a working day, the period expires at the end of the next working day.

**Plant**: Appliances and other machinery, and, where applicable under the law and/or practice of the state of the Contracting Authority, the temporary structures on the site required to carry out the works but excluding equipment or other items required to form part of the permanent works.

**Project Manager**: The legal or natural person responsible for monitoring the execution of the contract on behalf of the Contracting Authority, where the latter is not the Central Government Authority.

**Provisional sum**: A sum included in the contract and so designated for the execution of works or the supply of goods, materials, plant or services, or for contingencies, which sum may be used in whole or in part, or not at all, as instructed by the Engineer.

**Site**: The places provided by the Contracting Authority where the works are to be carried out and other places stated in the contract as forming part of the site.

**Special conditions**: The special conditions laid down by the Contracting Authority as an integral part of the tender document, amplifying and supplementing the general conditions, clauses specific to the contract and the terms of reference (for a service contract) or technical specifications (for a supply or works contract).

**Supervisor/Engineer**: The legal or natural person responsible for administering the contract on behalf of the Contracting Authority.

**Tender document/s**: The dossier compiled by the Contracting Authority and containing all the documents needed to prepare and submit a tender.

**Tender price**: The sum stated by the tenderer in his tender for carrying out the contract.

**Works**: Works of a permanent or temporary nature executed under the contract.

**Written communications**: Certificates, notices, orders and instructions issued in writing under the contract.
**Part XII - Separate packages in tender offer**

The procedure for the submission of separate packages in the tender offer is stipulated in Part XII of the Public Procurement Regulations (Legal Notice 296/2010), reproduced hereunder for ease of reference.

1. Contracting authorities listed in Schedule 1 shall ensure that for all tenders awarded by the open or restricted procedures with an estimated value of over two million euro (€2,000,000) or, at the discretion of the Director of Contracts, on tenders of a lower estimated value or on tenders awarded through the negotiated or competitive dialogue procedures, the tender conditions stipulate that tenders shall only qualify for consideration if they are submitted in separate and sealed packages as follows:

   (a) Package One: an original and valid tender bond (Bid Bond), duly executed in the form, for the amount and for the validity period stipulated in the official tender document;

   (b) Package Two: technical specifications including supportive literature, details, designs, samples and any other matter as requested in the tender documents; and

   (c) Package Three: completed price schedules and, or bills of quantities, form of tender, payment terms or other financial arrangements; any covering letter which may provide other pertinent details of a commercial nature.

2. In the process of adjudicating the tender, the packages for all tenderers shall be opened in public and in the sequence enumerated in the sub-regulation (1). When at any stage, any tenderer fails to comply with the tendering procedural requirements and, or with the specifications, the remaining packages in his tender offer are to be discarded unopened:

   Provided that the Director of Contracts or, with his authorization, any contracting authority, shall have the right to seek clarifications on points of a technical nature to enable a proper evaluation of any tender, which, however, would at that stage have already been declared to be basically compliant.

3. Any decision leading to the discarding of any tender during any stage of the process is to be given publicity at the office of the contracting authority or at the Department of Contracts as the case may be and the affected tenderer is to be informed of the decision within two working days of its publication.

4. A complaint by the affected tenderer and any person having or having had an interest in obtaining a particular public contract must reach the Review Board within ten calendar days from the date of notification of the decision, which complaint shall be communicated by the Secretary of the Review Board to the Department of Contracts at once. The complaint submitted to the Review Board shall be accompanied by a deposit of 0.5% of the estimated value of the tender as submitted by the tenderer, which deposit shall only be refundable if the Review Board finds in the tenderer’s or other person having or having had an interest in obtaining a particular public contract’s favour:

   Provided that the deposit shall in no case be less than ten thousand euro (€10,000) or more than fifty-eight thousand euro (€58,000).

5. The review is to be effected by the Public Contracts Review Board before the next stage of the adjudication process is commenced.

6. The procedure to be followed by the Board when carrying out the review shall consist in a complete and detailed re-examination of the reasons brought forward by the adjudication board of
any department or contracting authority for the discarding of any particular tender.

(7) In fulfilling this obligation the Chairman of the Review Board shall have the right to put appropriate questions to the Head of any department or contracting authority as well as the members of the respective adjudication boards and to have recourse to all pertinent documentation.

(8) The Chairman of the Review Board shall also have the right to seek expert advice from outside the department or contracting authority involved.

(9) The decision of the Board shall be final and binding on all parties and the award procedure shall proceed in accordance with its decision.

(10) Any tenderer or any other person having or having had an interest in obtaining a particular public contract whose complaint under this Part is not upheld shall have the right to have recourse to the procedure for appeals as provided for in Part XIII when the offer reaches the final stage of the award procedure, that is, the opening and the publication of the financial proposals.

Provided that any rights granted to tenderers by virtue of regulation 85(6) shall also apply to appeals decided by the Review Board under this Part:

Provided further that any tenderers whose complaint has been heard in terms of sub-regulation (4) may request a substitute of the members of the Review Board when appealing in terms of sub-regulation (10).

Part XIII - Appeals

The procedure for the submission of appeals is stipulated in Part XIII of the Public procurement Regulations (Legal Notice 296/2010), reproduced hereunder for ease of reference.

(1) Any tenderer or candidate concerned, or any person, having or having had an interest or who has been harmed or risks being harmed by an alleged infringement or by any decision taken including a proposed award in obtaining a contract or a cancellation of a call for tender, may file a notice of objection with the Review Board.

The notice shall be filed within ten calendar days following the date on which the contracting authority has by fax or other electronic means sent its proposed award decision. The communication to each tenderer of the proposed award shall be accompanied by a summary of the relevant reasons relating to the rejection of the tender as set out in regulation 44(3), and by a precise statement of the exact standstill period.

The notice of objection shall only be valid if accompanied by a deposit equivalent to one per cent of the estimated value of the tender submitted by the tenderer, provided that in no case shall the deposit be less than one thousand and two hundred euro (€1,200) or more than fifty-eight thousand euro (€58,000). The Secretary of the Review Board shall immediately notify the Director that an objection had been filed with his authority thereby immediately suspending the award procedure. The Department of Contracts or the contracting authority involved, as the case may be, shall be precluded from concluding the contract during the period of ten calendar days allowed for the submission of appeals. The award process shall be completely suspended if an appeal is eventually submitted.

(2) The procedure to be followed in submitting and determining complaints as well as the conditions under which such complaints may be filed shall be the following:

(a) any decision by the General Contracts Committee (or a Special Contracts Committee) and by a contracting authority, shall be made public at the Department of Contracts or at the office of the contracting authority prior to the award of the contract;

(b) the notice of objection duly filed in accordance with sub-regulation (1) shall be made public by the Review Board not later than the next working day following its filing;

(c) within three working days of the publication of the replies the Secretary of the Review Board shall prepare a report (the Analysis Report) analysing the letter of objection. This report shall be circulated to the persons who file an objection and interested parties. After the preparatory process is duly completed, the Head of the contracting authority shall forward
to the Chairman of the Review Board all documentation pertaining to the call for tenders in question including files, tenders submitted, copies of deposit receipts, any motivated letter, who shall then proceed as stipulated in Part XIV;

(d) the Director or the Head of the contracting authority shall publish a copy of the decision of the Review Board at his department or at the premises of the relevant contracting authority, as the case may be.

Copies of the decision shall be forwarded by the Secretary of the Board to the complaining tenderer, any persons who had registered or had an implied interest, the Director of Contracts and to the contracting authority concerned.
VOLUME 2 SECTION 1 - DRAFT CONTRACT FORM

Financed by: .......................................................... [Specify Source of Financing]
Project: .......................................................... [Title and Number]
Contract Number: ........................................... [Contract Number]

This contract is concluded between:

Department of Contracts
Notre Dame Ravelin
Floriana FRN 1600
Malta

(hereinafter called “The Central Government Authority”) on behalf of [name of Contracting Authority and address] on the one part, and

[Name of Contractor]
[Address]

(hereinafter called “The Contractor”) on the other part,

Whereas the Central Government Authority is desirous that certain supplies should be [supplied, manufactured, delivered, installed, commissioned, maintained, etc.] by the Contractor, viz.:

[Contract Title]

and has accepted a tender by the Contractor for the provision of such supplies and the remedying of any defects therein.

It is hereby agreed as follows:

1. In this contract words and expressions shall have the meanings assigned to them in the contractual conditions set out below.

2. The place of acceptance of the supplies shall be [.................................], the time limits for delivery shall be [.................................], and the INCOTERM2000 applicable shall be delivery duty paid (DDP).

3. The following documents shall be deemed to form and be read and construed as part of this contract, in the following order of precedence:

   (a) this contract,
   (b) the Special Conditions,
   (c) the General Conditions,
   (d) the technical specifications and design documentation,
   (e) the Contractor’s technical offer (including any clarifications made during adjudication),
   (f) the financial offer (after arithmetical corrections)/breakdown,
   (g) the tender form,
   (h) any other documents forming part of the contract.

Addenda shall have the order of precedence of the document they are modifying.

4. In consideration of the payments to be made by the Contracting Authority to the Contractor as hereinafter mentioned, the Contractor undertakes to deliver all supplies, and remedy defects therein in full compliance with the provisions of the contract.

5. The Contracting Authority hereby agrees to pay the Contractor in consideration of the execution and completion of the works and remedying of defects therein the amount of:
• Unit Contract price delivered to stores including VAT/other taxes): €...........................................

• Unit Contract price in words: ................................................................. Euro

or such other sum as may become payable under the provisions of the contract at the times and in the manner prescribed by the contract. VAT shall be paid in compliance with National Law (in particular the VAT Act 1998, the Act No X of 2003 and relevant Legal Notices).

The Contract shall run for a period of [ ] years, commencing from [date], with an option with the consent of the contractor for a further extension of six (6) months at the same rate and conditions of the original contract. Consignments are to be delivered to GHPS Stores, Guardamangia, or any other site as indicated by the GHPS on the relevant confirmation of order, after receipt of the relative requisition/s from the Government Health Procurement Services, in the quantities stated therein, within [ ] weeks unless otherwise stated in writing from receipt thereof.

In this connection, your attention is drawn to the relative clauses of the conditions of Contract dealing with your liabilities for delay in delivery and for abandonment of Contract.

Government reserves the right not to order the entire quantity tendered for, and the quantity ordered during the contract period could vary considerably from the figures quoted.

6. The Contractor hereby agrees to submit a performance guarantee amounting to €................. equivalent to 10% of the contract value together with the signed contract.

7. In witness whereof the parties hereto have signed the contract. This contract shall take effect on the date indicated on Contract Agreement.

Done in English in three originals: one for the Central Government Authority, one for the Contracting Authority, and one for the Contractor.

Central Government Authority: Contractor:
Signed by: Signed by:

........................................................................................................... .................................................................

In the capacity of: In the capacity of:

........................................................................................................... .................................................................

Being fully authorized by and acting on behalf of Being fully authorized by and acting on behalf of

........................................................................................................... .................................................................

Date: .................................................... Date: ....................................................
The full set of General Conditions for supply contracts can be viewed / downloaded from: www.contracts.gov.mt/conditions

It is hereby construed that the tenderers have availed themselves of these general conditions, and have read and accepted in full and without reservation the conditions outlined therein, and are therefore waiving any standard terms and conditions which they may have.

These general conditions will form an integral part of the contract that will be signed with the successful tenderer/s.
These conditions amplify and supplement, if necessary, the General Conditions governing the contract. Unless the Special Conditions provide otherwise, those General Conditions remain fully applicable. The numbering of the Articles of the Special Conditions is not consecutive but follows the numbering of the Articles of the General Conditions. Other Special Conditions should be indicated afterwards.

Article 2     Law and language of the contract
2.1     The laws of Malta shall apply in all matters not covered by the provisions of the contract.
2.2     The language used shall be English.

Article 4     Communications
All communications are to be addressed to
Director General (Contracts),
Department of Contracts,
Notre Dame Ravelin,
Floriana FRN 1600.

Telephone: 00356 2122 0212
Fax: 00356 21247681
Email: info@contracts.gov.mt

Article 7     Supply of additional documents (Not applicable)

Article 9     General obligations
Sub-article 9.6 is not applicable.

Article 11    Performance guarantee
11.1.1     The Contractor shall within 15 days of receipt of the notification of the award of the contract, furnish the Contracting Authority with a guarantee for the full and proper performance of the contract. The amount of the guarantee shall be 10% of the amount of the contract price, including any amounts stipulated in addenda to the contract. In the case that the value of the contract does not exceed Euros 10,000 no performance guarantee is required.
11.3     The performance guarantee shall be in the format given in Volume 2 Section 4 and shall be provided in the form of a bank guarantee.

Article 12     Insurance
Supplies shall be insured against all damages at all times. The contractor shall be responsible for all damages or loss in transit up to the delivery site.

Article 13    Performance programme
Orders will be placed according to the exigencies of the Government Health Procurement Services

Article 14    Contractor's drawings (Not applicable)

Article 15     Sufficiency of Tender prices
The tender price must cover the whole of the supplies as described in the tender documents.

Article 16    Tax and Customs Arrangements
All prices are to be quoted in Euro and are to be inclusive of all duties, taxes and any other charges if applicable.

Article 17    Patents and licences
Vide Volume 4 Section 3 - Technical Conditions
Article 18  Commencement order
18.1  Delivery of goods is to be effected upon receipt of confirmation of orders by Government Health Procurement Services.
18.2  The Contract will commence from the last date of the signature of the Contract, unless indicated otherwise in the Contract.

Article 19  Delays in Execution
19.1  Supplies are to be delivered within the stipulated delivery period as stated on Contract and subsequent confirmation of orders.

Article 22  Variations
Subject to the provisions of Article 78 of the Public Procurement Regulations 2010, the Contracting Authority reserves the right to vary the quantities specified. The unit prices used in the tender shall be applicable to the quantities procured under the variation.

Article 24  Quality of supplies
All items supplied are to conform with Volume 4 Section 3 (Technical Conditions).

Article 25  Inspection and testing
All items supplied are to conform with Volume 4 Section 3 (Technical Conditions).

Article 26  PAYMENTS - General principles
26.1  Payments shall be made in Euro currency. The Special Conditions shall lay down the administrative or technical conditions governing payments.
26.2  As per Clause 26.4.
26.3  As per Clause 26.4.
26.4  The payments shall be made as follows:
   The payment terms referred to under the relative Clause of the General Tender Conditions particular to this tender state that payment shall be effected within a reasonable period of time. This means that payment shall be effected within 150 days, provided that it is tied
   a)  to the actual date of the ‘physical receipt /acceptance’ of the ordered goods (or services rendered) which
   b)  shall be subject to conformity in all respects to all contractual obligations, specifications and conditions on the date of the ‘physical receipt/acceptance’ of the ordered goods (or services rendered) to the satisfaction of the Head of Department or his/her representative.

   In breach of this time limit, as qualified by provisos (a) and (b) here above, a Contractor would become entitled to the payment of 2% plus the European Central Bank’s main refinancing rate as published in the Official Journal. The ECB refinancing rate applicable is that in force on the first calendar day of the half year during which interest becomes due.

26.5  As per Clause 26.4.
26.6  For supplies not covered by a warranty period, the conditions to which final payments are subject, shall be as stated in Clause 26.4.
26.7  As per Clause 26.4.
26.8  Unless otherwise stipulated in the Special Conditions, contracts shall be at fixed prices, which shall not be revised.
26.9  As per clause 26.4.

Article 27  Payment to third parties (Not Applicable)

Article 28  Delayed Payments as per Clause 26.4 (a) and (b) above.

Article 29  Delivery
29.1  The Contractor shall bear all risks relating to the goods until provisional acceptance at destination. The supplies shall be packaged so as to prevent their damage or deterioration in transit to their destination.
29.2  As per specifications
29.3 The packaging shall become the property of the recipient subject to respect for the environment.
29.5 All items supplied are to conform with Volume 4 Section 3.
29.6 All items supplied are to conform with Volume 4 Section 3.

Article 31 Provisional acceptance - Not applicable

Article 32 Warranty Obligations
As per tender specifications and conditions at Volume 3 (if and where applicable).

Article 33 After-sales service
33.1 As per tender specifications and conditions at Volume 3.
33.2 As per tender specifications and conditions at Volume 3.

Article 41 Dispute settlement by litigation
Any dispute between the Parties that may arise during the performance of this contract and that has not been possible to settle otherwise between the Parties shall be submitted to the arbitration of the Malta Arbitration Centre in accordance with the Arbitration Act (Chapter 387) of the Laws of Malta.


Article 69 Checks and Audits by community bodies
Article 69 of General Conditions is not applicable.
VOLUME 2 SECTION 4 - SPECIMEN PERFORMANCE GUARANTEE

(LETTERHEAD OF THE REGISTERED FINANCIAL INSTITUTION PROVIDING THE GUARANTEE)

Director of Contracts
Department of Contracts
Notre Dame Ravelin
Floriana FRN1600
Malta

[Date]

Dear Sir,

Our Guarantee Number ................................ for €........................

Account: [Account Holder’s Name]

In connection with the contract entered into between yourself on behalf of the Director of Contracts and [Name and Address of Contractor] hereinafter referred to as “the Contractor” as per the latter’s tender and your acceptance under [CT File Reference], whereby the contractor undertook the [title of contract] in accordance with Article 13 of the Special Conditions the [works/services/supplies] as mentioned, enumerated or referred to in the Specification and/or Bills of Quantities forming part of the contract documents, we hereby guarantee to pay you on demand a maximum sum of €[amount in works and numbers] in case the obligations of the above-mentioned contract are not duly performed by the Contractor.

This guarantee will become payable on your first demand and it shall not be incumbent upon us to verify whether such demand is justified.

For avoidance of doubt it is hereby declared that although this instrument gives rise to legal relations between the guarantor and the beneficiary, it is hereby specifically declared for all intents and purposes of law that this guarantee does not exempt the above-mentioned Contractor from any obligations, acts of performance or undertaking assumed under the tender documents as ratified in the contract.

Any payments due to the contractor in respect of the obligations entered into under the contract above referred to shall be made through this Bank.

This guarantee expires on the [expiry date] and unless it is extended by us or returned to us for cancellation before that date any demand made by you for payment must be received in writing not later than the aforementioned expiry date.

This document should be returned to us on utilization or expiry or in the event of the guarantee being no longer required.

After the expiry date and in the absence of a written demand being received by us before such expiry date, this guarantee shall be null and void, whether returned to us or not, and our liability hereunder shall terminate.

This guarantee is personal to you, and is not transferable or assignable.

Yours Faithfully,

.............................................

[Signatory on behalf of Guarantor]
The BS/DIN Standards are only indicative and may be only replaced by the equivalent EN Standards. This is applicable in case of non-medicinal products only.

The quality of each offer will be evaluated in accordance with the Administrative and Evaluation Criteria as detailed in the grids included in this tender dossier. No other award criteria will be used. The evaluation of the technical offers will follow the procedures set out in the Public Procurement Regulations of 2010 (LN 296 of 2010).

<table>
<thead>
<tr>
<th>Item Description</th>
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<tr>
<td>Cochlear implants.</td>
</tr>
</tbody>
</table>

The Cochlear Implant System: should be able to provide a Cochlear Implant User with good hearing in quiet and from a distance and also should have increased performance in noise.

Implant:

The implant must have a high reliability: Implant survival rate, safety and reduced surgical risks are important. Data and statistics must be presented to support this, including data on medical and surgical complications which may eventually lead to problems requiring explantation which is not covered by the guarantee.

Electrodes should be designed to minimise the likelihood of non-auditory stimulation as a result of trauma to the cochlea which should also be minimal, therefore enhancing performance and increase preservation of residual hearing. Documentation should be provided to support this.

The implant should be able to withstand an impact of minimum 1.5 Joules without being damaged. This must be in accordance with the European standards for Cochlear implants EN45502-2-3:2010 Active Implantable Medical Devices, part 2-3.

It should be compatible with a 3 tesla MRI with the magnet removed and 1.5 tesla with the magnet in place. Please provide documentation to prove this. If removal of magnet is necessary safety and reduced risks should also be documented.
Compatibility to minimal invasive surgery is essential to reduce the risk of complications especially in children. The implant should be as small as possible, sealed in a titanium housing with a thickness less than 6mm and must weigh less than 9g.

Implant Identification should be an available option to reduce to risks of unpleasant stimulation from the wrong processor.

The option to map around problem electrodes should be possible to increase performance.

Documentation regarding the number of electrodes or stimulation channels and contact spacing must be provided to show evidence of better speech discrimination and patient satisfaction on the sound quality in most environments including Speech in quiet, Speech in Noise, Noise and listening to Music.

Stimulation Rate is important in providing better sound clarity, especially speech perception. The minimum limit accepted is 15,000pps but products which produce stimulation rates of above 30,000 will be preferred with documented evidence on the benefits of increased stimulation rates in comparison to lower stimulation rates and the effects on speech perception and clarity. Telemetry is an important feature by which the implant offers the possibility to make important measurements.

The Implant should be covered by at least a 10yr warranty were a replacement is to be provided by the supplier free of charge if there is mechanical or electrical defects or failure.

Features will be considered based on world wide research and documentation on the benefits which will improve the stimulation, less risk for patient and will result in quality, clarity and a fast rehabilitation of the patient.

**Processor:**

The Processor must be tamper proof. Easy monitoring of operating status should be possible especially by parents of children using the cochlear implant, resulting in confidence and better performance by the user/s.

The Sound Processor should be able to be secure in place especially in children. This will ensure continues hearing and prevent the implant from getting lost.
The Sound Processor should be protected against water damage, documentation to show this is important. Microphone must have added protection to reduce as much as possible wind noise.

Access to Loop systems, FM systems, and other audio devices should be available.

The Magnet should be easily adjusted by the user to reduce the likelihood of the coil falling off, but also to reduce skin irritation.

The option to choose between standard or rechargeable batteries should be available.

The sound processor should be able to adapt automatically to different acoustic environments. Documentation and worldwide research should be submitted to support this point.

Remote control of the sound processor is required and should be user friendly.

Different wearing configurations for the audio processor should be available to be worn at ear level or on the body. Considerations for infants and toddlers should be taken into account.

**Programming System:**

The software should support quick and automatic intra-operative measurements. Fitting of the sound processor using these measurements or even post-operative measurements is essential to provide infants with a good map as early as possible. This will also reduce initial over-stimulation.

These measurements should include:

- Standard Impedance
- Auditory Nerve Response Telemetry, appointments especially in Paediatric Cases.
- Electrically Evoked Stapedius Reflex Threshold
- Electrically Evoked Auditory Brainstem Response.

The programming software and hardware must be reliable, portable and user friendly. All necessary equipment must be provided, including portable equipment needed to use in the operating theatre.
Technical Specifications:

Sound Processor:
Analogue to Digital Converters: 16bit
Max IDR: 96dB
Max IIDR: 96dB
Microphones: Design with both omni-directional and directional options will be preferred.
Number Of independent Programs: 4
Telecoil built in: Yes
BTE colours: optional

Implant:

Case Material: Titanium / Ceramic

Number of Electrodes, Current sources, Stimulation modes and Stimulation rate: Depends on documentation and independent world wide studies.

Electrode Impedance Telemetry: Yes

Field Telemetry: Yes

Implant Identification: Yes

Electrode:

Placement: Perimodiolar / Lateral Wall

Electrode Number and Spacing, Active Electrode Length, Extra-cochlear electrodes: Depends on documentation and independent world wide studies

All Necessary training for Maltese Cochlear Implant team must be provided. The team includes Surgeons, Audiologists, Speech Pathologists. Continuing Professional Development must also be provided in this area and updates should also be provided. The training may include travelling abroad to different centres and international conferences.

Material for Rehabilitation should be provided, including week by week guides for both parents and professionals. Parent training aids are also important. These should be in the form of leaflets, books, cards, DVDs and other multimedia resources.

Professional and Clinical support must be available on request and immediately. This could be done by telephone or remotely. Local support should be also be available to give immediate help to Audiology Unit and local suppliers should have a good understanding and experience with these devices and parts.

All interested candidates must provide a Quality Certification and standards must be based on the relevant European standards. All products must carry the CE-mark.

Forecast consumption for 1 year: a) 5 Bilateral implants; b) 5 Unilateral implants.
Delivery within 6 - 8 weeks from confirmation of order.

Minimum order quantities are not acceptable to GHPS. GHPS reserves the right to accept or reject offer according to the exigencies of the Department.

SAMPLES REQUIRED
(TO BE SUBMITTED WITHIN 2 DAYS UPON NOTIFICATION ONLY)

<table>
<thead>
<tr>
<th>ITEM</th>
<th>QUANTITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nil</td>
<td>Nil</td>
</tr>
</tbody>
</table>

Since no samples are required for this tender, clauses related to submission of samples are not applicable.
The contract shall run for a period of 36 months commencing on the later date showing on contract. Tenderers are advised to note carefully all relevant conditions and to proceed by submitting the information requested hereunder.

The annual quantity indicated is the forecast consumption for one year. It is therefore to be clearly understood that the quantity purchased by Government during the contract period may vary considerably according to the needs of the Department depending on the actual consumption of the item.

The tenderer shall quote one Unit Price applicable for the year/s as requested on the Financial Bid.

The supplies must comply fully with the technical specifications as indicated above and conform in all respects with the indicative quantities, samples and other instructions.

Delivery is to be effected to G.H.P.S. - Guardamangia/Marsa/Madliena or any other site as indicated on Confirmation of Order.

Interested parties are requested to submit with their offer Literature / Documentation / Package / insert and labelling (as applicable) in English. Otherwise offers will not be considered. Samples of the item are to be submitted upon notification.

In the case of suppliers who are already supplying the product being offered, the tenderer may be exempted from submitting samples. However the specific brand name and the respective reference of the Letter of Acceptance/Contract must be clearly indicated in the tender submission.

Samples submitted by unsuccessful tenderers and which have not been used for adjudication purposes are to be withdrawn within 14 days from date of notification, failing which such item will become the sole property of the Government of Malta.

Samples are not to be considered as forming part of any eventual purchases. Compensation for samples submitted will only be applicable when the value of the sample exceeds 1% of the total contract price.

Samples should be clearly marked as ‘SAMPLES’ with the name of Tenderer and tender Reference numbers. Samples, whenever requested, should be submitted at the Government Health Procurement Services, G’Mangia Malta, within two (2) working days of notification. Tenderers are to be given a receipt for the samples delivered.

In instances where the Department deems fit, the Director GHPS may, with the consent of the contractor, extend the contract period by a further six (6) months at the same price rates and under all the original contract conditions.

It shall be lawful for the Head of Department to reject without the necessity of prior legal proceedings any consignment or part thereof, which in his opinion does not possess the qualities required under the contract and to obtain it elsewhere, at any price, and on contractor’s account, should the latter fail to replace the articles rejected within the time allowed for the purpose by the Head of Department.

The name and address of the manufacturer and the country where the goods will be manufactured shall be furnished. Failure to give this information may involve non-consideration of the tender. Full specifications of the product offered shall be submitted.
Part 2 - The Contractor’s Technical Offer

In the space provided, tenderer is to submit the description and details of the item/s being offered.
VOLUME 4 SECTION 1 - FINANCIAL BID

Breakdown of Costs
All prices to be submitted in Euro Currency

1. Price delivered to stores/site inclusive of VAT, Customs Duty & any other charges (if any):

<table>
<thead>
<tr>
<th>Item Number</th>
<th>Item</th>
<th>Unit Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>Cochlear implants bilateral</td>
<td>€</td>
</tr>
<tr>
<td>1b</td>
<td>Cochlear implants unilateral</td>
<td>€</td>
</tr>
</tbody>
</table>

* Applicable as indicated on Contract Agreement.

The unit referred above is per quantity ........................................ (Quantity to be specified)

(Prices must be worked out as requested, otherwise offer will not be considered.)

3. Pack Size:

3. Validity of Offer: 180 days from Closing Date of Tender

Signature: ........................................................................................................

(the person or persons authorised to sign on behalf of the tenderer)

Date: ........................................................................................................
VOLUME 4 SECTION 2 - DECLARATION SHEET
NON-MEDICINAL PRODUCTS

If this is not completed in ALL respects, where applicable, offer will not be considered.

1: GHPST NO: ................................................................................................................................................

2: Name of Product: ........................................................................................................................................

Brand: ............................................................................................................................................................

3: Manufacturer: ..................  Country of Manufacture (Origin): .................................

4: Product conforms with regulations on CE marks:  Yes ☐  No ☐

OTHERS (specify): ...........................................................................................................................................

N.B. The BS/DIN Standards are only indicative and may be only replaced by the equivalent EN Standards. This is applicable in case of non-medicinal products only.

5: Pack size: ..................................................................................................................................................

6: Package insert in English/Maltese language:  Yes ☐  No ☐

7: Total Product Shelf Life: .................................  Years

- Products having a shelf life of 30 months or less must not be more than \(\frac{1}{6}\)th expired upon delivery to Stores.
- Products having a shelf life over 30 months must not be more than \(\frac{1}{3}\)rd expired upon delivery to Stores.

In cases where the Marketing Authorisation Holder (MAH) / Manufacturer submits written evidence in the quote that lead time prior to release is 2 months or more, the product must not be more than \(\frac{1}{3}\)rd expired upon delivery to Stores.

8: I confirm that in case of award of Contract, Delivery Period shall be that specified at Volume 3 in the Technical Specifications.  Yes ☐  No ☐
I undertake to ensure that the above will be part of the Contractual obligations in the event of an award.

Signature of Tenderer

Tel No: ............................................

Police/Trading licence no.: .....................................

VAT Registration no.: ...........................................

Date: ......................................................

Name in Capital Letters

Fax No: ............................................

Validity Date: ...........................................

Validity Date: ...........................................

Date: ......................................................

Rubber Stamp or Company Name in Capital Letters
A. TECHNICAL CONDITIONS

1 Standards

1.1 Medicinal Products
All medicinal products should meet those standards laid down in the latest edition of European Pharmacopoeia (Ph.Eur.) or, in the absence of which, other pharmacopoeia acceptable to the Superintendent of Public Health. In the event that neither of the above is available, an in-house company monograph may be considered.

1.2 Medical Devices
Medical devices should, where applicable, bear the CE mark and must meet those standards established by Maltese legislation or standards acceptable to the appropriate competent authority in Malta.

2 Legal Classification

2.1 The Department shall accept the classification of the product being offered as determined by the competent authority in Malta.

2.2 The Responsible Person / Qualified Person and the Licensee of the Wholesale Dealer and/or the Tenderer must complete Declaration Sheet at Volume 4 Section 2. The tenderer must also complete the Financial Bid at Volume 4 Section 1.

3 Packaging and Labelling

3.1 Medicinal Products
The following particulars shall appear on the “outer packaging” of a medicinal product, or where there is no outer packaging on the “immediate packaging” in one of the official languages of Malta.

(i) the “name of the medicinal product”, which must be followed by the “common name” when the product contains only one active ingredient and if the name of the product is an invented name. If a product is available in more than a single pharmaceutical form and/or strength, the pharmaceutical form and/or strength must be included in the respective labelling.

(ii) a statement of the active ingredients expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight using their common names.

(iii) the pharmaceutical form and contents by weight, by volume or by number of doses of the product.

(iv) the route/s of administration must be clearly shown.

(v) a special warning that the medicinal product must be stored out of reach of children, where appropriate.

(vi) a special warning, if this is necessary, for the medicinal product concerned.

(vii) the expiry date in clear terms by month and year.

(viii) the manufacturer’s batch number.

(ix) special storage precautions / conditions.

(x) special precautions for disposal of unused medicinal products or waste material derived from such products, if appropriate.

(xi) the name and address of the manufacturer and/or marketing authorisation holder.

(xii) In the case of radiopharmaceuticals the outer carton and the container shall be labelled in accordance with the regulations for the safe transport of radioactive materials laid down by the International Atomic Agency. In addition the labelling on the shielding shall explain in full the codings used on the vial and shall indicate, where necessary, for a given time and date, the amount of radioactivity per dose or vial and the number of capsules, or for liquids, the number of millilitres in the container. The vial shall be labelled with the name or code of the product, including the name or chemical symbol of the radionuclide; the batch identification and expiry
date; the international symbol for radioactivity; the name of the manufacturer; and the amount of radioactivity.

Where appropriate, a package insert in one of the official languages of Malta must accompany each medicinal product.

3.2 **Medical Devices**
All medical devices offered must comply with Maltese legislation currently in force.

4 **Monographs**
4.1 **Medicinal Products**
The Department reserves the right to request a true copy of the company in-house monograph.

5 **Certificates**
5.1 **Medicinal Products**
It is the responsibility of the Responsible Person/Qualified Person to make available the batch specific Quality Control Certificate upon request by the Government Health Procurement Services.

5.2 **Medical Devices, Food Supplements, Chemicals and Disinfectants**
The necessary documentation as determined by the competent authority in Malta is to be submitted by the tenderer.

6 **Quality and Safety**
6.1 **Medicinal products**
The Responsible Person/Qualified Person must inform the Government Health Procurement Services, within 12 hours of having come into possession, of any information concerning batch defects and withdrawal of the product from the market.

6.2 **Medical Devices**
The tenderer must inform the Government Health Procurement Services, within 12 hours of having come into possession, of any information concerning batch defects and withdrawal of the product from the market.

7 **Samples and Literature**
All samples are to be submitted to the Director, Government Health Procurement Services, St Luke’s Square, Guardamangia, PTA1010 within two (2) working days from notification.

7.1 **Medicinal Products**
The tenderer must ensure that the following is submitted with each offer:

(i) Original/true copy of the outer packaging and immediate packaging labelled in one of the official languages of Malta.

(ii) Original/true copy of the package insert in one of the official languages of Malta.

(iii) Original/true copy of the Summary of Product Characteristic and patient information leaflet (PIL) in one of the official languages of Malta.

(iv) In cases were specification state that product must be delivered with an administration set/delivery system, tenderer is to provide a sample or detailed literature of the device.

7.2 Supplier is to submit original certificate and declaration stating whether the product conforms to the special conditions for the purchase of blood products, unless the product is registered in Malta and/or another EU country.

7.3 Supplier is to submit a certified true copy of the MA/QL/PI issued by the Licensing Authority of Malta signed by the Responsible Person of the tendering company.

7.4 In case of medicinals manufactured under ‘special’ licence or where a medicinal product supplied is licensed in a third country, supplier is to submit a batch specific Certificate of Analysis with each consignment.

7.5 **Medical Devices**
The tenderer must ensure that a sample accompanies each offer.

8 **Summary of Product Characteristics/Data Sheet**
8.1 **Medicinal Products**
In case of an award of tender, the tenderer must ensure that a copy of the latest approved European Summary of Product Characteristics (SPC) or a Product Data Sheet intended for the use of healthcare professionals is kept at all times by the tenderer, where such tenderer is established in Malta, or by the pharmaceutical wholesale dealer appointed as per Condition 9.1, when the tenderer is not established in Malta.

The tenderer or the appointed pharmaceutical wholesale dealer, as applicable, must make the SPC or Data Sheet available without delay and on request to healthcare professionals in Government employment to permit appropriate use of the medicinal product offered. When the SPC or Data Sheet is updated or revised during the period of validity of the contract, the tenderer or the appointed pharmaceutical wholesale dealer, as applicable, must make available to healthcare professionals already supplied with a SPC or Data Sheet, a copy of the updated or revised SPC or Data Sheet.

B. SPECIAL CONDITIONS

9 Pharmaceutical Wholesale Dealer

9.1 Medicinal Products

A tenderer established in Malta must be duly licensed as a pharmaceutical wholesale dealer by the competent authority in Malta. When the tenderer is not established in Malta he must appoint a pharmaceutical wholesale dealer duly licensed by the competent authority in Malta in order to act on his behalf to import the medicinal product into Malta and to deliver the product to the Government Health Procurement Services. In this respect, Part II and Part III of Declaration Sheet at Volume 4 Section 2 are to be duly filled in.

The Licensee and the Responsible Person/Qualified Person of the local pharmaceutical wholesale dealer/importer must ensure that Maltese legislation, conditions of licence and other requirements that may be issued from time to time by the Superintendent of Public Health or the competent authority in Malta are abided with within the definitions of their individual responsibilities.

9.2 Item offered must be licensed by Closing Date of tender. A copy of the MA/QL/PI issued by the licensing authority of Malta is to be submitted with offer.

10 Delivery

10.1 Delivery of goods

Consignments of goods must be strictly delivered in boxes that are appropriately packed to withstand transport and handling. Delivery of consignments on pallets must be made on Euro pallets.

The Government Health Procurement Services reserves the right to make any claims on discrepancies in the quantity of items delivered within 48 hours of receipt of goods at the stores.

When consignments are to be delivered via containers, the tenderer should inform in writing the relative stores of the date of delivery and the number of consignments a minimum of one week in advance. The Government Health Procurement Services reserves the right to refuse such consignments if prior notification is not effected. Expenses and responsibility for refused items shall be borne by the tenderer.

10.2 DH markings

Each unit container or pack is to be marked ‘DH’. Markings are to be printed in an indelible medium on the outer packaging of each item and must be clearly legible, otherwise the products will be rejected upon delivery. Expenses and responsibility for refused items shall be borne by the tenderer.

When the packaging of a consignment is opened to place DH markings on unit containers or packs, the goods must be re-packaged again in the same manner as the original packaging of the manufacturer or supplier.

11 Shelf life

The total product shelf life must be clearly indicated in the Tender documents submitted. Products having a shelf life of 30 months or less must not be more than 1/4th expired upon delivery to Stores.

Products having a shelf life over 30 months and/or containing blood products, must not be more than 1/3rd expired upon delivery to Stores.

In cases where the Marketing Authorisation Holder (MAH) / Manufacturer submits written evidence in the quote that lead time prior to release is 2 months or more, the product must not be more than 1/3rd expired upon delivery to Stores.
Any infringement in this respect will render the tenderer liable to a penalty of 5% of the value of the consignment, together with any other damages suffered by the Government Health Procurement Services.

The Government Health Procurement Services reserves the right to refuse any consignment which does not satisfy these conditions.

12 Batch Numbers
Each consignment delivered to the Government Health Procurement Services must be physically segregated according to batch numbers and must be clearly documented. Each bulk packaging (carton box) must be labelled with the batch number and quantity of items contained therein.

The Government Health Procurement Services reserves the right to refuse any consignment comprising more than two different batch numbers.

13 Preparations requiring cold storage
The actual date and time of arrival of these preparations must be notified in advance, thus enabling proper arrangements for their storage. Such products must be appropriately packed and must include specific storage instructions that are clearly indicated on the bulk packaging.

In case of medicinal products, a declaration must be submitted by the Responsible Person/Qualified Person stating that the storage status for such preparations has been maintained as required throughout the delivery. The Government Health Procurement Services reserves the right to refuse consignments not abiding with the above conditions at the expense of the tenderer.

C. OTHER CONDITIONS

14 Marine Cargo Insurance
All bidders are to ensure that deliveries to GHPS are adequately insured.

D. DEFINITIONS

i. “medicinal product” means a) any substance or combination of substances presented for treating or preventing disease in human beings, b) any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings.

ii. “responsible person” means a person registered as a pharmacist with the Pharmacy Council and recognised as suitable by the Medicines Authority since such person possesses adequate knowledge of the conditions required for the storage and distribution of medicinal products in order to avoid their deterioration or damage, has adequate knowledge of the regulations concerning the distribution of medicinal products, and has knowledge and understanding of good distribution practice.

iii. “outer packaging” means the packaging into which is placed the immediate packaging.

iv. “immediate packaging” means the container or other form of packaging immediately in contact with the medicinal product.

v. “name of the medicinal product” means the name given to a medicinal product, which may be an invented, common or scientific name together with a trademark or the manufacturer’s name; the invented name shall not be liable to confusion with the common name.

vi. “common name” means the international non-proprietary name recommended by the World Health Organisation, or if one does not exist, the usual common name.

vii. “qualified person” means a person performing duties as specified in the Medicines Act especially with respect to importation of medicinal products coming from outside the EU/EEA.


ix. “Marketing Authorization (MA)” is the licence for medicinal products to be placed on the market in Malta granted by the Medicines Authority in accordance with the Medicines Act, 2003 (Act No III of 2003 and subsidiary legislation) and for Centrally Authorized products, by the European Medicines Agency
(EMA). Currently the three main types of procedures recognized for the granting of a marketing authorization and to place a product on the market in Malta are the National Procedures, European Procedures (Mutual Recognition and Decentralized Procedures), and Centralized Procedure.


xi. “Parallel Importation (PI)” is the importation from an EU Member State or a country within the EEA of a medicinal product, which is already authorised on the Maltese-market, by an importer who is someone other than the importer, appointed by the marketing authorisation holder of the product on the Maltese-market. The medicinal product may then be parallel imported in Malta provided that the importer obtains a licence to market the product.

xii. “Special Medicines” These are unlicensed medicinal products, which may be needed to treat patients with special clinical needs that cannot be met by other medicinal products. They do not have a marketing authorisation in the country where they are manufactured but they are produced by a Manufacturer holding a “specials” licence.

xiii. “Third Country” A country that is not an EU Member State or within the EEA.

E. NOTICE

General Conditions/Special Conditions also apply in so far as they are not inconsistent with the above Conditions, in which case, the above Conditions shall be followed in preference to the General/Special Conditions.
SPECIAL CONDITIONS FOR THE SUPPLY OF BLOOD PRODUCTS/DERIVATIVES

Original declarations from the manufacturer, in reply to the following queries, are to be submitted with each offer:

1. indicate the countries in which the product is in use.
2. indicate whether the product is in use in the country of origin.
3. indicate whether the product is manufactured from the same donor pool and source plasma used for residents of the country of origin.
4. indicate whether the donors are voluntary or not, and whether they are paid or reimbursed; preference will be given to source plasma from voluntary and non-paid donors.
5. state whether products from same batch of source plasma are used in the country of manufacture.
6. state whether each plasma donor has been tested and found negative for HBsAg, Anti-HIV 1, 2 and subtype O, Anti-HCV, and other tests which might be implemented as routine screening test for donors in the future.

Note: only batches derived from plasma pools tested and found non-reactive for HCV RNA by CAT, using validated test methods of suitable sensitivity and specificity, should be batch released by the Marketing Authorisation holder (as from 01/01/99).

7. indicate the source of origin of the plasma stating specifically the exact country/ies of origin of the plasma source. Plasma derived products from countries with very low BSE prevalence will be given preference.
8. state the expiry date of the product, which must have a shelf-life of at least two years and ideally four years, when delivered.
9. supply documentation regarding details and number of methods used to sterilise and virally inactivate the blood products, as well as documents on their efficacy. Documents must also state that the normal therapeutic properties of this product are retained. The Department reserves the right to accept only the blood product which it considers to be the most appropriate on the grounds of safety.
10. state whether sero conversions for HIV 1, 2 and subtype O, Hepatitis B, Hepatitis C are known to have occurred in patients receiving this product and when. If no sero conversions are known to have occurred, the tenderer is to make clear statement to this effect.
11. supply 3 vials of the product for local clinical trial, with full descriptive literature.
12. clearly state and indicate that products supplied are also in conformity with the latest European Pharmacopoeia standards for blood products.
13. supply certificate of Good Manufacturing Practice and Free Sales Certificates from Health Authority of the country of origin.
14. ensure that the products supplied by them are as safe as the best scientific state of the art can make them. Their falling short of these standards could also make suppliers liable to pay any sums in damages which any such action or non-action might have caused the Maltese Government to pay.
15. ensure that the blood products requiring refrigerated storage are transported at a temperature of 2 °C - 8 °C at all times, including the delivery of these products to the Government Health Procurement Services.
16. clearly state and confirm that the product complies with each of the above conditions, as otherwise the offer may not even be considered.
17. each consignment delivered is to be accompanied by an Original Declaration stating that the specific batch numbers delivered are manufactured from plasma originating from the type of donors as specified in original quote.
18. products delivered must be accompanied by an independent Certificate of Analysis from an accredited laboratory.
19. genetically engineered products may be preferred to products which are derived from human plasma or to products which contain human derivatives as an excipient.
20. manufacturer is to keep tenderer, and consequently the Department, informed of any changes in the product during the contract period.

The conditions set out in the tender should not in any way be interpreted as exonerating the Fractionation Centre, Supplier, Manufacturer from ensuring that the best possible precautions available are used to ensure that the products are in no way contaminated and safe for use on patients.