UNICEF TECHNICAL REQUIREMENTS FOR MEDICAL DEVICES (MD)

February 2016

This document was developed for suppliers and products to comply with, in the context of UNICEF Quality Policy for procurement and supply. It adopts the guidance of the International Medical Device Regulators Forum (IMDRF)\(^1\) to ensure safety performance, quality and equity in UNICEF’s procurement of medical devices.

A. Technical requirements for medical devices (MD)

1. **Conformity with Quality Management System (QMS) standards**
   Suppliers/Manufacturers shall conform to at least one of the following quality management system standards:
   
   a. **For products classified as medical devices**: ISO 13485: Medical devices - Quality management systems -- Requirements for regulatory purposes.

   b. **For other devices**: ISO 9001 Quality management systems – Requirements for regulatory purposes.

   **N.B.** – UNICEF is aware of the changes being implemented by the EU with regards to the Medical Devices and IVD Directives. As these changes take shape and the new Regulations are adopted and implemented by Notified Bodies and subsequently Certifying Bodies, UNICEF reserves the right to request information from current or future suppliers on how they plan to accommodate the changes so that appropriate ISO certification is maintained.

2. **Conformity with product standards**:
   a. The manufacturer should hold the product technical documentation as per the IMDRF/GHTF requirements (goods that do not meet these standards shall not be acceptable to UNICEF):

<table>
<thead>
<tr>
<th>SG1/N11:2008</th>
<th>Summary Technical Documentation (STED) for demonstrating conformity to the Essential Principles of Safety and Performance of Medical Devices</th>
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<tbody>
<tr>
<td>SG1/N68:2012</td>
<td>Essential Principles of Safety and Performance of Medical Devices</td>
</tr>
<tr>
<td>SG1/N77:2012</td>
<td>Principle of Medical Devices Classification</td>
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   b. The product(s) shall conform to the standards stipulated by the International Organisation for Standardisation (ISO) and/or equivalent standards as recognised by the IMDRF\(^1\).

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\(^1\) The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011, to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and to accelerate international medical device regulatory harmonization and convergence. IMDRF: [http://www.imdrf.org](http://www.imdrf.org).

\(^2\) Entity that provides goods and/or services
c. The labelling of the product shall meet the requirements described in the regulations of at least one of the 5 regulatory authorities listed below (or at a minimum with SG1-N70:2011: Label and Instructions for Use for Medical Devices):

1) Australia: Therapeutic Goods Administration (TGA);
2) Canada: Health Canada;
3) European Union: Regulatory agency in the European countries;
4) Japan: Pharmaceuticals and Medical Devices Agency (PMDA)
5) USA: Food and Drug Administration (FDA).

d. Any medical device registered for “Research Use Only” or “For export only” is not acceptable, unless specifically authorised in writing by UNICEF.

3. **Product(s) compliance with regulatory requirements for market approval**
Product(s) shall be cleared by at least one of the 5 regulatory authorities mentioned above and comply with the corresponding market release certificates (listed below) as described in the GHTF for market clearance:

1) Australia: TGA Device Licence;
2) Canada: Device Licence;
3) European Union: CE 93/42 Medical Device Directive (MDD) Mark;
4) Japan: Device Licence;
5) USA: 510k market clearance.

4. **Product(s) documentation**
   a. UNICEF shall ask for the WHO pre-qualification award letter if applicable.
   b. Product(s) shall conform to design, functionality and intended use stated by the manufacturer and the technical specifications stated by UNICEF.
   c. UNICEF may ask for additional test reports for specific products deemed high risk in the context of UNICEF’s scope of activities.

5. **Product(s) shelf life**
   a. The supplier shall provide the total product shelf life in months (as applicable).
   b. The supplier shall ensure that a minimum of two thirds of the shelf life remains at delivery.

6. **Sterile consumables/renewables**
   a. The supplier shall provide certificates issued by the manufacturer of all sterile devices in accordance with ISO 11135 and ISO 11137: Sterilization of health care products (as applicable).
   b. The supplier shall provide batch release certificates for each batch delivered to UNICEF.

7. **Hazardous goods**
The supplier shall provide the material safety data sheet (MSDS) issued by the manufacturer, including section 14 completed: Transport information (as applicable).

8. **Product(s) modifications**
The successful bidder who is awarded a Long Term agreement shall notify UNICEF any major product modification, such as branded name, marketing clearance or any approval certification.

9. **Sustainable production/distribution**
As UNICEF moves towards the implementation of Sustainable Developmental Goals, it is keenly interested in the efforts made by manufacturers and suppliers towards sustainable initiatives. Thus, as an asset, but not a requirement, the supplier is encouraged to provide information on the
implementation of sustainability in the production and distribution phases of the procurement cycle, with an emphasis on social and environmental responsibility.

B. Attachments that shall be submitted with the offer

1. **Proof of conformity to Quality Management System (QMS) standards**
   a. **Supplier**: Valid ISO 13485 or ISO 9001 certificate (as applicable) including scope. Copy in English.
   b. **Manufacturer**: Valid ISO 13485 certificate. Copy in English.

2. **Proof of product conformity to product standards**: As described in the technical specifications.

3. **Proof of product compliance with regulatory requirements for market approval**: A valid certificate from one of the five founding members of the GHTF. The certificate shall indicate:
   i. Name of regulatory authority
   ii. Market clearance with licence number

4. **Product documentation**:
   a. **WHO Pre-qualification**: As described in the technical specifications.
   b. **General**:
      Product information (data) sheet. Completed as in the tender solicitation documents.
      i. Supplier's product reference & short description;
      ii. Manufacturer's product reference & short description;
      iii. Supplier's contact details, including link to web site with product catalogue;
      iv. Manufacturer's contact details, including link to web site with product catalogue;
      v. Claimed intended use.
      vi. Contact details of the person appointed for vigilance purposes (customer complaints and recall).
   c. **Technical specifications**:
      Supplementary documents as requested in the tender.
      i. Complete technical specification, including technical data sheet;
      ii. List of all supporting items/devices required, but not supplied;
      iii. Recommended storage/transport conditions; Temperature and humidity;
      iv. Waste management: Recommended safe and responsible method of waste disposal;
      v. Instructions for use and training material in English, French or Spanish;
      vi. Installation and training;
      vii. Service and Maintenance;
      viii. Brochure (showing the product reference);
      ix. Published field testing studies not older than 2 years;
      x. Estimated weight and volume;
      xi. Packaging photos of primary and secondary packaging with legible labelling.

5. **Product(s) shelf life**: Supplier shall provide the total product shelf life in months (as applicable).

6. **Sterile consumables/renewables**
   A copy of the certificate of sterilisation, indicating:
a. UNICEF purchase order number and item number;
b. Manufacturer’s product reference and product short description;
c. Manufacturing site/sterilisation site;
d. Certification of the sterilization site (ISO 13485), including the standards applied for the sterilization process;
e. Batch number (lot number);
f. Batch quantity;
g. Date of sterilisation;
h. Expiry date (month, year);
i. Sterilisation method;
j. Process (standard) followed for validation and routine control of sterilisation for medical devices;
k. Process (standard) followed for medical devices to be labelled “sterile” (EN 556-2:2003 Sterilization of medical devices: requirements for medical devices to be designated “STERILE“- requirements for aseptically processed medical devices); and
l. Name of the person responsible for the final release (title, date and signature).

7. Hazardous goods: Supplier shall provide the hazardous classification (MSDS), including section 14 completed: Transport information (as applicable).

8. Sustainable Goals: Indicate the company’s efforts to implement any of the following in the coming 12 months:
   a. Environmental management: Plans to obtain the Environmental Management System certificate, ISO 14001 or equivalent with CO₂ reduction targets. Specify which areas will be covered.
   b. Standards: Plans to conform to the Standards of Social Accountability e.g. SA8000 or ISO 26000, or other standards that demonstrate commitment to social responsibility. Specify which areas will be covered.
   c. Global initiatives: Plans to join the Global Reporting Initiative and/or the United Nations Global Compact.
   d. Other related information: Other plans related to sustainable production/distribution.