# ANNEX SUP 11-3: Template for Advertisement of Business Opportunities for Medical Devices

**Information on business opportunities for the supply of medical devices**

**Date:** <insert >

**Reference no:** <insert>

**Subject: Supply of <commodity> for <name of program>**

**Contracting Authority:** <insert>  
**Deadline for submission of letter of interest:** <insert>

<Brief description of the project, funding, and other relevant information>

<Name of the Contracting Authority>,<country>, in cooperation with its partner <name of partner> invites qualified suppliers of one or several of the following medical devices to respond to this advertisement. Qualified suppliers shall meet essential requirements as described by the Global Harmonization Task Force (GHTF). Suppliers who have responded to this advertisement and provides the required information may be invited to participate in the procurement procedure for the relevant lot(s).

Medical devices needed:

* <description of product>
* <description of product>
* <description of product>

***(Note: divide into lots according to the Procurement Plan)***

The supplier shall provide documentation that the product(s):

1. Is produced in conformity with at least one of the following standards ISO13485/2003; Japan QS Standard for medical devices 1128, the FDA QS (21 CFR part 820), and/or other equivalent standards which are in conformity with the GHTF[[1]](#footnote-2) essential requirements.
2. Is recognised and marketed according to at least one of the regulatory authorities: MPALS License (Australia), Device License (Canada), CE Mark (EU), Device License (Japan), and 510 k Device Letter (USA).

The interested supplier shall provide the following information to the Contracting Authority using the contact details below:

* Complete the Contractor Registration Form available from the Contracting Authority.
* Indicate which supplies or service you are interested in supplying.
* Provide documentation that the product complies with the requirements stated under the scope of point 1 and 2
* Provide documentation of countries of export for the specific product(s)
* If the supplier is not the manufacturer of the product the Manufacturer’s Authorization shall be submitted.

Only suppliers who can meet the above requirements and provide documentation will be short listed to receive a Request for Quotation with full details.

This is purely information on business opportunities and does not constitute a commitment to purchase or any other form of contractual commitment with the Contracting Authority.

Any subsequent contract will be subject to the <Name of the Contracting Authority> General Terms and Conditions for contracts and the Code of Conduct for Contractors, available at the following link. Printed versions are available on request.

<https://www.kirkensnodhjelp.no/en/about-nca/for-contractors/>

<Name of the Contracting Authority>

<Address, country>

<Phone, fax no., email>

<Contact person>

1. *(GHTF, SG1- N041R6 – essential principles of safety and performance medical devices (including In Vitro diagnostic devices) 2004.*

   *and GHTF SG1(PD) - N043R6 – labelling for medical devices (including In Vitro diagnostic devices) 2004.*  [↑](#footnote-ref-2)