**Annex 12. Questionnaire for Medical Device/Equipment**

*All documents submitted must be in English or be accompanied with certified translation.*

**PART I – Submitter and manufacturer information**

**Submitter:**

Name of submitter: Click here to enter text.  
Address: Click here to enter text.  
Contact person’s name: Click here to enter text.  
Email: Click here to enter text.  
Phone: Click here to enter text.  
  
Status of the submitter:

Legal manufacturer Yes ☐ No ☐  
 or

Distributor – Trader Yes ☐ No ☐

**Legal manufacturer:**

Name of manufacturer: Click here to enter text.  
Country: Click here to enter text.   
Address (office): Click here to enter text.  
Address (manufacturing site(s)): Click here to enter text.  
Contact person’s name: Click here to enter text.  
Email: Click here to enter text.  
Phone: Click here to enter text.

**PART II – Device identification**

**Device Identification** (Trade name, Type, Model, Product Code, Reference(s))**:**Click here to enter text.

**Intended use / purpose:** Click here to enter text.

**Product details** (material, dimensions, etc.)**:***(E.g. If stainless steel product, identify AISI type or composition. If plastic product, identify grade or composition)*Click here to enter text.

**Device classification** (specify the related regulation, e.g. MDD, FDA, Other)

**EU 93/42/EEC** directive, Rule# (according to MDD annex IX)

Class: Click here to enter text.

**FDA:**

Product code: Click here to enter text.  
Regulation number: Click here to enter text.  
Product class: Click here to enter text.

**Other regulation** (specify): Click here to enter text.

**Nomenclature code** (if known – specify GMDN, UMDNS or other): Click here to enter text.

# Part III – Quality Management System Certification

**Legal Manufacturer:**

1. ISO 9001 Yes ☐ No ☐
   1. Certification body: Click here to enter text.
   2. Expiration date: Click here to enter text.
2. ISO 13485 Yes ☐ No ☐
   1. Certification body: Click here to enter text.
   2. Expiration date: Click here to enter text.
3. ISO 14001 or plans for this Yes ☐ No ☐
   1. Certification body: Click here to enter text.
   2. Expiration date: Click here to enter text.
4. ISO 50001 or plans for this Yes ☐ No ☐
   1. Certification body: Click here to enter text.
   2. Expiration date: Click here to enter text.

**If the manufacturing processes are subcontracted:**

| **Subcontracted activity / process** | **Name / address of the subcontractor** | **QMS certification of the subcontractor** |
| --- | --- | --- |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |

**Submitter** (if the submitter is not the legal manufacturer):

1. ISO 9001 Yes ☐ No ☐
   1. Certification body: Click here to enter text.
   2. Expiration date: Click here to enter text.
2. ISO 13485 Yes ☐ No ☐
   1. Certification body: Click here to enter text.
   2. Expiration date: Click here to enter text.

## Part IV – Regulatory certification

Is the **device CE marked?** Yes ☐ No ☐

For devices other than Class I excluding Class I sterile devices / Class I with measuring function / Class I reusable surgical instruments

Nature of the EC certification (MDD 93/42/EEC): Annex II.3 ☐ Annex V ☐

Identification of the Notified Body (+ identification number): Click here to enter text.

Is the device **FDA** approved? Yes ☐ No ☐

For FDA approved device: Manufacturer name: Click here to enter text.

Manufacturer listing #: Click here to enter text.

If the device is “510k cleared”, indicate the 510k clearance #: Click here to enter text.   
 If the device is “PMA cleared”, indicate the PMA clearance #: Click here to enter text.

**Other regulatory** clearance / registration (specify Canada, Japan, Australia): Click here to enter text.

Applicable regulation: Click here to enter text.

Certification / license number: Click here to enter text.

## Part V – Compliance to technical standards

If the declaration of compliance is based on report(s) issued by an independent testing laboratory, the reference of the test report must be indicated (mandatory for safety compliance of electro-medical devices)

| **Standard # and date** | **Fully or partially applied** | **Identification of the Testing laboratories, where used** | **Test report reference** |
| --- | --- | --- | --- |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |

## Part VI – Other information

### VI-1 INSTALLATION / SPARES / SERVICE

1. Is installation necessary? Yes ☐ No ☐

Specify tools required (if Yes): Click here to enter text.

2. Is training required? Yes ☐ No ☐

Specify who will provide training and specify costs if applicable: Click here to enter text.

3. Are spare parts available? Yes ☐ No ☐

Specify source and if additional costs required: Click here to enter text.

Specify period supply of spare parts is guaranteed: Click here to enter text.

4. Information available on service/maintenance? Yes ☐ No ☐

Attached information: Click here to enter text.

1. Electrical Medical Device/Equipment Yes ☐ No ☐

Specify voltage and frequency available: Click here to enter text.

Specify all plug types available: Click here to enter text.

### VI-2 DECONTAMINATION

Only for re-usable devices.

1. Specify method for cleaning: Click here to enter text.
2. Specify instructions for disinfection: Click here to enter text.
3. Specify any restrictions on detergent/disinfectant types: Click here to enter text.
4. Specify sterilization method required before re-use: Click here to enter text.

### VI-3 WARRANTY

Specify recommended maximum number of uses or years of use or period of use:   
 Click here to enter text.

### VI-4 SAFE DISPOSAL

Specify instructions for safe disposal: Click here to enter text.

## Part VII. Commitment and authorization

### VII-1 Commitment

I, the undersigned, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ acting as responsible for the company \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,

certify that the information provided (above) is correct and true,

**☐** and I certify that the product offered is identical in all aspects of manufacturing and quality to that marketed in \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*country of origin*), including disease category type, intended use, intended population, specimen type, method and site of manufacture, sources of materials, quality control of the product and starting material, packaging, shelf-life and product information.

**☐** and I certify that the product offered is identical to that marketed in *(name of country)*, except:

(e.g., state the stipulated exception)

If any changes occur to the information after the submission of this product questionnaire, the manufacturer/supplier undertakes to provide the relevant update as soon as possible.

Date: Signature:

### VII-2 Power of attorney

The manufacturer authorizes a distributor to submit the questionnaire

Date: Signature:

Distributor (Signed by Distributor for Manufacturer under power of attorney)

Please provide a copy of the power of attorney.

**Checklist of Required documentation:**Documents to be submitted must be true and valid copies.

☐ Copy of manufacturing licence

☐ Letter of authorization to act on behalf of manufacturer if submission is not from the manufacturer

☐ Copy of ISO 9001 certificate (for manufacturer and for trader)

☐ Copy of ISO 13485 certificate (for manufacturer and for trader)

☐ Complete and detailed technical specifications of the product (incl. **manufacturer’s product code**)

☐ **CE certificate** (additionally for EC class III items EC Design Dossier)

☐ Declaration of conformity (signed and dated, according to ISO 17050, specifying the relevant directives, regulations and standards, and attaching copy of certificates)

**☐** Manufacturer’s EC Representative (EC Rep) contact details and country information

**☐ FDA 510k Premarket approval device letter/ Device licence (Australia, Japan, Canada)**

**☐** Evidence that product has been sold to Europe or U.S. or other large market areas with strong regulatory systems.

☐ Evidence of clinical studies to all but class I non-sterile, non-measuring medical devices: e.g. a copy of study results

☐ Product technical data sheet

☐ **Photos of the product, packaging and labelling** at various angles if necessary

☐ Instruction for use in English, Spanish and French

☐ User, installation and/or assembly manual, if applicable

☐ Service/repair (after sale) services with contact details, if applicable

☐ Information on cleaning, disinfecting and sterilization methods (for reusable devices only)

☐ Certificates for product-specific safety standards, such as ISO 10993-1.

☐ Certificate for sterilization process, such as ISO 17665 (Steam sterilization), ISO 11135 (ETO sterilization), ISO 11137 (Gamma Irradiation), or other equivalent.

☐ Manufacturer’s Post-market study report from 3 last years

☐ Quality Assurance process (for the manufacturer and/or for the trader)

S. Specify any other documentation provided (e.g. any test results or relevant standards):

☐ ISO 14001. If not available, a signed commitment letter from a manufacturer

☐ Other relevant certificates related to Environmental and/or Energy management, such as ISO 50001, or FSC certificates for the carton and paper used in packaging (for manufacturer and for trader).

☐ Manufacturer’s copy of the latest audit report (audited by an European health product distributor)

☐ Copy of third party laboratory test reports, if available (Laboratory name and ISO 17025 accreditation status), if applicable.