### Annex-4: Questionnaire for Electrical or Battery Operated Equipment

**PART I – Bidder and device identification**

**Device Identification** (Trade name, Type, Model, Product code, Reference(s)):

**Identification of the bidder:**

Name:

Address:

Status:

Legal manufacturer:

or

Distributor – Trader:

If the Submitter is not the legal manufacturer, then indicate the legal manufacturer:

**Device category:** (Generic group of devices):

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

93/42/EEC directive:

 Class: Rule# (according to MDD annex IX):

FDA:

 Product code:

Regulation number:

Product class:

Other regulation (specify):

**Nomenclature code** (if known – specify GMDN, UMDNS or other):

**PART II – Quality Management System Certification**

**Legal Manufacturer:**

1. ISO 9001 [ ]  Yes [ ] No

a. Certification body:

b. Expiration date:

2. ISO 13485 [ ]  Yes [ ] No

a. Certification body:

b. Expiration date:

3. ISO 14001 or plans for this [ ]  Yes [ ] No

a. Certification body:

b. Expiration date:

4. ISO 50001 or plans for this [ ]  Yes [ ] No

a. Certification body:

b. Expiration date:

**If the manufacturing process(es) is(are) subcontracted**:

|  |  |  |
| --- | --- | --- |
| Subcontracted activity / process | Name / address of the sub- contractor | QMS certification of the subcontractor |
|  |  |  |
|  |  |  |
|  |  |  |

**Bidder** (if the bidder is not the legal manufacturer):

1. ISO 9001 [ ]  Yes [ ] No

a. Certification body:

b. Expiration date:

2. ISO 13485 [ ]  Yes [ ] No

a. Certification body:

b. Expiration date:

**PART III – Regulatory certification**

**Is the device EC marked?** [ ]  Yes [ ] No

 For devices other than Class I, and Class I sterile devices / Class I with measuring function:

 Nature of the EC certification (MDD 93/42/EEC):

[ ]  Annex II.3 [ ]  Annex V

 Identification of the Notified Body (+ identification number):

**Is the device FDA approved?** [ ]  Yes [ ] No

 For FDA Class I device:

Manufacturer name:

 Manufacturer listing #:

 If the device is “510k cleared”, indicate the 510k clearance #:

**Other regulatory clearance / registration** (specify Canada, Japan, Australia, …):

 Applicable regulation:

 Certification / license number:

**If the device contains lithium metal and lithium ion batteries**

* Does it comply with clause 38.3 of the recommendations on “Transport Of Dangerous Goods” from the United Nations? [ ]  Yes [ ] No
* Does it comply with the latest IATA Dangerous Goods Regulations (DGR)?

 [ ]  Yes [ ] No

**PART IV – 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 |
|  |  |  |  |
|  |  |  |  |

**Part V – Other information**

**V-1 INSTALLATION / SPARES / SERVICE**

1. Is installation necessary [ ]  Yes [ ] No

Specify tools required (if Yes):

2. Is training required? [ ]  Yes [ ] No

Specify who will provide training and specify costs if applicable:

3. Are spare parts available? [ ]  Yes [ ] No

Specify source and if additional costs required:

Specify period supply of spare parts is guaranteed:

4. Information available on service/maintenance? [ ]  Yes [ ] No

Attach information:

5. Specify voltage and frequency available:

Specify plug supplied:

**V-2 DECONTAMINATION (Only for re-usable devices)**

Specify method for cleaning:

Specify instructions for disinfection:

Specify any restrictions on detergent/disinfectant types:

Specify sterilization method required before re-use:

**V-3 WARRANTY**

Specify recommended maximum number of uses or years of use or period of use:

**V-4 SAFE DISPOSAL**

Specify instructions for safe disposal: