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: