**QUOTATION REQUEST FOR CERTIFICATION OF MEDICAL DEVICES ACCORDING TO ISO 13485/9001 AND**

**DIRECTIVE 93/42/EEC or DIRECTIVE 98/79/EC**

In order for us to provide an accurate quote, we need to determine the processes and activities that are involved within your organisation**.**

Please provide us with as much information as you can by answering the following questions. If you have any questions, please contact the sender of this form.

*Sections 1 and 2 are valid for all services. Sections 3, 4 and 5 are valid when certification is done according to the MDD Directive.*

# Section 1:

|  |
| --- |
| **Basic contact information** |
| **Legal Manufacturer Name:** |  |
| **Contact Name:** |  | **Position:** |  |
| **Address:** |  |
| **Telephone Number:** |  |
| **E-mail Address:** |  |
| **Website Address:** |  |
| **Total No of Employees:** |  | **No of Shifts:** |  |

**Activity distribution and/or multi-site addresses where no. 1 is the main site:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Site Number** | **Multi-site address** | **Process description\*** | **Same Quality system?** | **No of employees** | **No of Shifts** |
| **1** |  |  |  |  |  |
| **2** |  |  |  |  |  |
| **3** |  |  |  |  |  |

**\*Process description:** Design / Development / Manufacturing / Installation/Servicing / Distribution **/** Sterilisation / Clean room / Sales

# Critical subcontractor of crucial supplier outsourced processes and material/components:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Site Number** | **Critical subcontractor address** | **Process description\*** | **ISO 13485****Certified\*\*** | **No of employees** | **No of Shifts** |
| **1** |  |  |  |  |  |
| **2** |  |  |  |  |  |
| **3** |  |  |  |  |  |

***\*Process description:*** *Design / Development / Manufacturing / Installation/Servicing / Distribution / Sterilisation / Clean room / Sales*

**\*\*ISO 13485 Certified:** *Please attach a copy of the certificate held by subcontractor/supplier, if any.*

**ISO 13485 Certification scope** (covering processes and categories of devices):

**Description of all product lines** (number(s) / process(es)):

|  |
| --- |
| **Section 2: Services requested** |
|  | **Services:** |
| **We would like to apply for the following:** | ☐ | Medical Devices Directive - 93/42/EEC (EU/EEA) |
| ☐ | In Vitro Diagnostics medical devices Directive - 98/79/EC |
| ☐ | EN ISO 13485:2016 | We are already certified by: |  | Exp. Date: |  |
| ☐ | ISO 9001:2015 | We are already certified by: |  | Exp. Date: |  |
| ☐ | MDSAP |
| ☐ | Other | Specify: |  |
| **Product lifecycle status:** | ☐ | First time certification. |
| ☐ | The products have been certified by another certification body. We would like Presafe to takeover certification. |
| ☐ | Own Brand Labelling’ of a product which is already certified. |
| ☐ | Other | Specify: |  |
| ☐ | The product(s) has/have already been tested. Reports will be enclosed as a part of the technical documentation. |

**Section 3: List of devices to be certified**

*The guidance documents mentioned below can be found at the Commission web site* [*http://ec.europa.eu/growth/sectors/medical-devices/documents/index\_en.htm*](http://ec.europa.eu/growth/sectors/medical-devices/documents/index_en.htm)

|  |
| --- |
| ***Please tick if the Medical Device incorporates:*** |
| Medicinal Substances by meaning of 2001/83/EC. Please refer to MEDDEV 2.1/3 | Yes | No |
| Animal Tissue. The use of animal tissue must be justified. Specify the type of animal tissue.If Regulation No 722/2012 is applicable, clinical evaluation for justification of use must be included. Please refer to MEDDEV 2.11/1 | Yes | No |
| HSA or Blood Derivate, *justification for use to be described and attached* | Yes | No |
| Natural Rubber Latex. Please refer to MEDDEV 2.5/9 | Yes | No |
| Will the device fall under the definition of a machine as defined in the Machinery Directive 2006/42/EC? | Yes | No |
| Is the device also a Personal Protective Equipment? | Yes | No |
| Is the clinical data according to literature route? | Yes | No |
| Is the clinical data based on own clinical studies? | Yes | No |
| Technical documentation shall be in English | Yes |  |

|  |
| --- |
| **List of Medical devices to be certified***(All types, variations and models. Please extend the table if more space is needed or include a print out of the full list of devices from your system)* |
| **Description of the medical device with intended use and mode of action. Instruction for use or leaflet shall be attached***Composition indicating concentration of substance(s) and/or material(s) shall be described when it is relevant.* | **Model/variants to be certified** | **Medical Device Class and MD Code** |
| **\* Rule** | **\* Class** | **Sterile** | **\*\*MD and MDS****code acc. to NBOG** | **GMDN****code****(Class IIa products)** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

\* Please refer to Annex IX of the directive and MEDDEV 2.4/1 rev 8 part 1 and part 2 for guidance <http://ec.europa.eu/health/medical-devices/documents/guidelines/index_en.htm>and also Manual on borderline <http://ec.europa.eu/health/medical-devices/files/wg_minutes_member_lists/borderline_manual_ol_en.pdf>

\*\*See <http://www.nbog.eu/resources/NBOG_BPG_2009_3.pdf>for the codes, MSD-CP-194

# Section 4: Conformity assessment procedure

## When product certification according to directive for medical devices 93/42/EEC, the manufacturer chooses the procedure based on the class of the medical device and preferred option:

**Please indicate preference – medical devices:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Class** | **Procedure** | **Procedure** | **Procedure** |
| ☐ | **I sterile** | ☐ | Annex V + VII | ☐ | Annex VI + VII | ☐ | Annex II excl. section 4 |
| ☐ | **I measuring** | ☐ | Annex V + VII | ☐ | Annex VI + VII | ☐ | Annex II excl. section 4 |
| ☐ | **IIa** | ☐ | Annex V + VII | ☐ | Annex VI + VII | ☐ | Annex II excl. section 4 |
| ☐ | **IIb** |  | ☐ | Annex II excl. section 4 |
| ☐ | **III** | ☐ | Annex II, incl. section 4 |

**Please indicate preference - IVD:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Class** | **Procedure** | **Procedure** | **Procedure** | **Procedure** |
| ☐ | **List A** | ☐ | Annex IV | ☐ | Annex V+ Annex VII | ☐ |
| ☐ | **List B** | ☐ | Annex IV | ☐ | Annex V+Annex VI | ☐ | Annex V+Annex VII | ☐ |  |
| ☐ | **Self testing device** | ☐ | Annex IV | ☐ | Annex V+Annex VI | ☐ | Annex V+Annex VI | ☐ | Annex III+Product DesignExamination |

**Section 5: Other information:**

|  |  |  |
| --- | --- | --- |
| **We would like to hear more about the following:** |  | Product Certification process |
|  | Management Systems Certification Services |
|  | Courses |

**Section 6: Declaration from the manufacturer:**

|  |  |  |
| --- | --- | --- |
| **We declare and understand the following** |  | We have not filed an application for the content of this quotation to another Notified Body. |
|  | We are obliged to fulfil the requirement of an approved quality management system and to keep it adequate and efficient. |
|  | We will ensure post market follow up, including provisions for clinical evaluation. We are obliged to notify competent authorities of incidents which might lead to the death of patient or user, to a serious deterioration of patient state of health or incidents that lead to systematic recall of same type of devices. |

**Please sign and date the request:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name:** |  | **Position:** |  |
| **Signature.** |  | **Date:** |  |

The information supplied above will be used to provide you with a quotation for our certification services. This quotation is totally dependent upon the information given above. We must therefore reserve the right to amend our quote should the information be found to be inaccurate or incomplete.

|  |  |
| --- | --- |
| **Please return the completed for to us at:** | *e-mail: presafedk@presafe.com* |