Dear Customer, in order to allow us to issue you an offer, we ask you to send this questionnaire filled via fax to number

+39 02-66101479 or by email to: [magni@italcert.it](mailto:magni@italcert.it). For further information you can to contact us to number +39 02 66104876

# Organization Data

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Company Name** |  | | | |
| **Registered Office (address)** |  | | | |
| **(if different by Registred office) Operative Unit / headquarters**  **object of certification\*** |  | | | |
| **Phone Numbers** |  | **Fax:** |  | |
| **Email for communications** |  | | | |
| **Reference for relations/communications with Italcert** |  | | | |
| **People (employees and not employees) at full time involved in requested certification activities:** | | | |  |
| **People (employees and not employees) at part time involved in requested certification activities:** | | | |  |
| **Average time (expressed as % of the full-time working hours) of the employment of people working part-time** | | | |  |
| **Average Time (in percent respect to full-time people) of activities of part time people** | | | |  |
| **(if it’s applicable) Number of work shift and respective time slot** | | | |  |
| **Average annual revenue (expressed in millions of euros) of last two years** | | | |  |

### \* If there are other operational sites, please also complete the second page of the questionnaire

**Medical Devices according to Directive 93/42/EEC**

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| **MEDICAL DEVICES for which certification is requested**  **(to explicit the intended use)**  (If deemed necessary, attach to the present section of the questionnaire all the documentation deemed useful for detailing the information requested (instructions for use / commercial documentation etc ...) | |  | | | | | | |
| **Classification of medical devices** | |  | | | **Rule of classification (according to annex IX of directive 93/42/CEE e s.m.i.)** | |  | |
| **INDICATE EXPLICITLY ALSO THE NUMBER OF TECHNICAL DOCUMENTS THAT HAVE BEEN PREPARED AND WHICH WILL BE PRESENTED AT ITALCERT FOR THE CERTIFICATION OF THE ABOVE DEEDS:** | | | | | | | **N°\_\_\_\_\_\_** | |
| **Procedure of Certification** | **Annex II (complete - with point 4 Examination of the design of the product)** | | | | | | | |
| **Annex II (excluding point 4)** | | | **Annex V** | | | **Annex VI** | |
| **limited sterilization requirements (I STERILE)** | | **limited metrological requirements (I m)** | | | **directive 93/42/EEC art. 12.3** | | |
| **Is the organization already in possession of a certificate that it intends to transfer to ITALCERT? (attach a copy of the current certificate to this form)** | | | | | | | SI | NO |

**Please check the boxes in order to associate NBOG 2009-3 codes to the medical devices**

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| **General non-active – non-implantable medical devices** | |  |
| MD0101 | Non-active devices for anaesthesia, emergency and intensive care |  |
| MD0102 | Non-active devices for injection, infusion, transfusion and dialysis |  |
| MD0103 | Non-active orthopaedic and rehabilitation devices |  |
| MD0104 | Non-active medical devices with measuring function |  |
| MD0105 | Non-active ophthalmologic devices |  |
| MD0106 | Non-active instruments |  |
| MD0107 | Contraceptives Medical Devices |  |
| MD0108 | Non-active medical devices for disinfecting, cleaning, rinsing |  |
| MD0109 | Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) |  |
| MD0110 | Non-active medical devices for ingestion |  |

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| **Non-Active implants** | |  |
| MD0201 | Non-active cardiovascular implants |  |
| MD0202 | Non-active orthopaedic implants |  |
| MD0203 | Non-active functional implants |  |
| MD0204 | Non-active soft tissue implants |  |

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| **Devices for wound care** | |  |
| MD0301 | Bandages and wound dressings |  |
| MD0302 | Suture material and clamps |  |
| MD0303 | Other medical devices for wound care |  |

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| **Non-active dental devices and accessories** | |  |
| MD0401 | Non-active dental equipment and instruments |  |
| MD0402 | Dental materials |  |
| MD0403 | Dental Implants |  |

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| **General Active Medical Devices** | |  |
| MD1101 | Devices for extra-corporal circulation, infusion and haemopheresis |  |
| MD1102 | Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia |  |
| MD1103 | Devices for stimulation or inhibition |  |
| MD1104 | Active surgical devices |  |
| MD1105 | Active ophthalmologic devices |  |
| MD1106 | Active dental devices |  |
| MD1107 | Active devices for disinfection and sterilisation |  |
| MD1108 | Active rehabilitation devices and active prostheses |  |
| MD1109 | Active devices for patient positioning and transport |  |
| MD1110 | Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) |  |
| MD1111 | Software |  |
| MD1112 | Medical gas supply systems and parts thereof |  |

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| **Monitoring devices** | |  |
| MD1301 | Monitoring devices of non-vital physiological parameters |  |
| MD1302 | Monitoring devices of vital physiological parameters |  |

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| **Devices for radiation therapy and thermos therapy** | |  |
| MD1401 | Devices utilising ionizing radiation |  |
| MD1402 | Devices utilising non-ionizing radiation |  |
| MD1403 | Devices for hyperthermia / hypothermia |  |
| MD1404 | Devices for (extracorporeal) shock-wave therapy (lithotripsy) |  |

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| **SPECIFICS OF MEDICAL DEVICES** | |  |
| MDS7001 | Medical devices incorporating medicinal substances, according to Directive 2001/83/EC |  |
| MDS7002 | Medical devices utilising tissues of animal origin, including Commision Regulation (EU) No 722/2012 |  |
| MDS7003 | Medical devices incorporating derivates of human blood, according to Directive 2000/70/EC amended by Directive 2001/104/EC |  |
| MDS7004 | Medical devices referencing the Directive 2006/42/EC on machinery |  |
| MDS7006 | Medical devices in sterile condition |  |
| MDS7007 | Medical devices utilizing micromechanics |  |
| MDS7008 | Medical devices utilising nanomaterials |  |
| MDS7009 | Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed |  |
| MDS7010 | Medical devices incorporating software / utilising software / controlled by software |  |

**Quality Management System**

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| **Field of Quality Management System proposed** | |  | | | | | |
| **(if applicable) Business processes entrusted to third parties (outsourcing) - attach certifications of the outsourcers** | |  | | | | | |
| **Certification standards** | | **ISO 13485:2016** | | **ISO 9001:2015** | |  | |
| **Is the organization already in possession of a certificate that it intends to transfer to ITALCERT?** | | | | | | YES | NO |
| **If so, indicate the name of the CAB and the expiry of the certificate** | | |  | | | | |
| **(if applicable) Name of the consulting firm** | | |  | | | | |
| **The Organization:** | He is responsible for the design of the product / service | | | | It carries out its activities on specifications already defined and / or supplied by the client | | |

# ADDITIONAL ELEMENTS (to be filled in only if they fall within the types considered below)

# MULTISITE ORGANIZATION

|  |  |
| --- | --- |
| Address 2nd site: |  |
| Reference |  |
| Performed activity: |  |

|  |  |
| --- | --- |
| Address 3rd site: |  |
| Reference |  |
| Performed activity: |  |

**List of authorizations required to perform the activity directly related to the certification object.**

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| According to the D.L. 196 of 30.06.2003, Art. 13, we inform you that the data you provide are collected by ITALCERT with the sole purpose of carrying out administrative / accounting procedures and to comply with the duties requested by ACCREDIA as a Certification Body . The data we request is essential for the management of the certification process. The transmission of the present application is equivalent to an implicit assent to the processing of your data. In case of certification, the related data (company name, address, validity and certificate number) will be made public. ITALCERT ensures at all times the exercise by you of the rights referred to in Art. 7 of the D.L. 196 of 30.06.2003. The data controller is ITALCERT, Viale Sarca 336, Milan. |

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| Filled by: |  | Date: |  |