

Annex 1 of the Certification/Recertification Application

ADDITIONAL INFORMATION FOR THE ORGANIZATION THAT REQUIRE CERTIFICATION/RECERTIFICATION OF a

Quality Management System –Medical Devices (QMS – MD)

**2. Scope of activity that is to be certified in compliance with *SR EN* ISO 13485:*2016***

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*Note: The activities performed with medical devices shall be ticked (Chart 1 ), and the categories of the MD domains from the portfolio (Chart 2 ) ,specifying : the usual name of the products, incadrarea intr-una din cele trei Directive Europeane referitoare la DM ,clasa de risc ( I ,IIa ,IIb sau III ) ,daca se supun si altor reglementari (ex :DM cu radiatii ionizante sau DM cu functii de masurare sau DM sub presiune ), daca sunt livrate steril,etc .*

*The field of activity to be certified results from the combination of activities with the fields of Medical Devices.*

**Table no.1-ACTIVITIES WITH MEDICAL DEVICES**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Medical Devices research-development-design |  | Medical Devices import |
|  | Medical Devices production |  | Medical Devices storage |
|  | Medical Devices mounting |  | Medical Devices distribution/commerce |
|  | Medical Devices service |  |  |
|  | Installation |  |  |
|  | Commissioning |  |  |
|  | Service |  |  |
|  |  |  |  |

**Tabel no. 2 - SCOPES FOR MEDICAL DEVICE**

| Main technical areas | Technical areas | Products categories covered by the technical areas | |
| --- | --- | --- | --- |
| 1. Non-active medical devices | 1.1. General non-active, non-implantable medical devices | Non-active devices for anaesthesia, emergency and intensive care |  |
| Non-active devices for injection, infusion, transfusion and dialysis |  |
| Non-active orthopaedic and rehabilitation devices |  |
| Non-active medical devices with measuring function |  |
| Non-active ophthalmologic devices |  |
| Non-active instruments |  |
| Contraceptive medical devices |  |
| Non-active medical devices for disinfecting, cleaning, rinsing |  |
| Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) |  |
| inactive medical devices for ingestion |  |
| 1.2. Non-active implants | ***Non-active cardiovascular implants*** |  |
| ***Non-active orthopaedic implants*** |  |
| Non-active functional implants |  |
| **Non-active soft tissue implants** |  |
| 1.3. Devices for wound care | Bandages and wound dressings |  |
| Suture material and clamps |  |
| Other medical devices for wound care |  |
| 1.4. Non-active dental devices and accessories | Non-active dental equipment and instruments |  |
| Dental materials |  |
| **Dental implants** |  |
|  | 1.5 Inactive medical devices other than those specified above |  |  |
| 2. Active medical devices (not-implantable) | 2.1. General active medical devices | Devices for extra-corporal circulation, infusion and haemopheresis |  |
| Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation, anaesthesia |  |
| Devices for stimulation or inhibition |  |
| Active surgical devices |  |
| Active ophthalmologic devices |  |
| Active dental devices |  |
| Active devices for disinfection and sterilisation |  |
| Active rehabilitation devices and active prostheses |  |
| Active devices for patient positioning and transport |  |
| Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) |  |
| software |  |
|  | medical gas supply systems and parts thereof |  |
| 2.2. Devices for imaging | *Imaging devices utilising ionizing radiation* |  |
| Imaging devices utilising non-ionizing radiation |  |
| 2.3. Monitoring devices | Monitoring devices of non-vital physiological parameters |  |
| Monitoring devices of vital physiological parameters |  |
| 2.4. Devices for radiation therapy and thermo therapy | **Devices utilising ionizing radiation** |  |
| Devices utilising non-ionizing radiation |  |
| **Devices for hyperthermia / hypothermia** |  |
| **Devices for (extra corporal) shock-wave therapy (lithotripsy)** |  |
| 2.5. Active medical devices (not-implantable) others than the ones previously mentioned | |  |
| 3. Active implantable medical devices | 3.1. General active implantable medical devices | ***Active implantable medical devices for stimulation / inhibition*** |  |
| ***Active implantable medical devices delivering drugs or other substances*** |  |
| ***Active implantable medical devices***  ***substituting or replacing organ functions*** |  |
| 3.2. Implantable medical devices, others than the ones previously mentioned | |  |
| 4. In vitro  diagnostic medical devices,  (IVD) | 4.1. Reagents and reagent products, including related calibrators and control materials, for determining:  Clinical Chemistry | |  |
| Immunochemistry (Immunology) | |  |
| Haematology /Haemostasis/ Immunohematology | |  |
| Microbiology | |  |
| Infectious immunology | |  |
| Histology/Cytology | |  |
| Genetic testing | |  |
| 4.2. In vitro diagnostic instruments and software | |  |
| 4.3. IVD medical devices, others than the ones previously mentioned | |  |
| 5.Sterilization methods for medical devices | 5.1. Ethylene oxide-gas sterilization (EOG) | |  |
| 5.2. Moist heat | |  |
| 5.3. Aseptic processing | |  |
| **5.4. Radiation sterilization (e.g.. gamma, X ray, electron beam)** | |  |
| 5.5. Sterilization methods, other than the ones previously mentioned | |  |
| 6. Devices incorporating/ using specific substances /technologies | ***6.1. Medical devices incorporating medicinal substances*** | |  |
| ***6.2. Medical devices utilising tissues of animal origin*** | |  |
| ***6.3. Medical devices incorporating derivates of human blood*** | |  |
| ***6.4. Medical devices utilising micromechanics*** | |  |
| ***6.5. Medical devices utilising nanomaterials*** | |  |
| ***6.6. Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed*** | |  |
| 7.Parts or services | Raw material (Raw metals, plastic, wood, ceramic) | |  |
|  | Components (Electrical components, fasteners, shaped raw materials, machined raw materials and moulded plastic) | |  |
|  | Subassemblies (Electronic subassemblies mechanical subassemblies, made to drawings and/or work instructions) | |  |
|  | Calibration services (Verification/confirmation services for measuring instruments, tools or test fixtures) | |  |
|  | Distribution services (Distributors providing storage and delivery of medical devices, not acting as a ‘legal manufacturer’ for medical devices) | |  |
|  | Maintenance services (Electrical or mechanical repair services, facility cleaning and maintenance services, uniform cleaning and testing of ESD smocks) | |  |
|  | Transportation services (Trucking, shipping, air transportation service in general) | |  |
|  | Other services (Consulting services related to medical devices, packaging services, etc.) | |  |

|  |  |
| --- | --- |
| How many distinct medical devices your portfolio contains? |  |

|  |  |  |
| --- | --- | --- |
|  | YES | NO |
| Can they be grouped in subcategories or in generic groups of devices? |  |  |
| Is your organization’s activity performed with medical devices that are fall under the provisions of European Directive 93/42/EEC or of |  |  |
| European Directive 98/79/EEC or of |  |  |
| European Directive 90/385/EEC? |  |  |
| The medical devices from your portfolio are classified in which one of the risk categories mentioned below? |  |  |
| I |  |  |
| IIa |  |  |
| IIb |  |  |
| III |  |  |
| The medical devices from your portfolio are regulated, besides the three European directives, by other regulation as X-ray apparatus (ionized radiation) or |  |  |
| As under pressure apparatus or with measurement function? |  |  |
| Do you introduce on the market and/or put into functioning sterile medical devices? |  |  |