|  |  |  |
| --- | --- | --- |
| **ANNEX 1**  **TO APPLICATION FOR VALUATION OF CERTIFICATION COSTS AT PCBC S.A.**  ***After completing the Application by the CUSTOMER - proprietary information***   |  |  | | --- | --- | | **POLISH CENTRE FOR TESTING AND CERTIFICATION**  469 Puławska Street; 02-844 Warsaw  +48 22 464 52 00 / e-mail: [pcbc@pcbc.gov.pl](mailto:pcbc@pcbc.gov.pl) | **MANAGEMENT SYSTEM CERTIFICATION DEPARTMENT**  e-mail: sprzedaz@pcbc.gov.pl | |

**refers to EN ISO 13485:2016**

1. **ORGANIZATION**

|  |  |
| --- | --- |
| Name of the Organization according to the National Court Register (registration document) |  |

1. **TECHNICAL AREAS AND RISK CLASSIFICATION CONFORMING TO THE ORGANIZATION PROFILE IN THE PRODUCTION / SERVICES AREA**  *(tick* ***ALL*** *appropriate)*

***Data source: IAF MD 9***

|  |  |  |
| --- | --- | --- |
| The main technical areas defined in 1-6 relate to finished medical devices defined as any medical device or accessory of any medical device | | |
| Technical area | Medical devices names in accordance with the scope submitted for certification | Risk classification \* |
| 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 orthopedic 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) |  |  |
| Non-active medical devices for ingestion |  |  |
| 1.2. Non-active implants | | |
| Non-active cardiovascular implants |  |  |
| Non-active orthopedic 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 devices/equipment and instruments |  |  |
| Dental materials |  |  |
| Dental implants |  |  |
| 1.5. Non-active medical devices other than specified above | | |
| Concise specification of the purpose the medical device | Medical devices names in accordance with the scope submitted for certification | Risk classification \* |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| Technical area | Medical devices names in accordance with the scope submitted for certification | Risk classification \* |
| 2. Active Medical Devices (Non-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 sterilization |  |  |
| 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, including medical device software design |  |  |
| Medical gas supply systems and parts thereof |  |  |
| 2.2. Devices for imaging | | |
| Devices utilizing ionizing radiation |  |  |
| Devices utilizing non-ionizing radiation |  |  |
| 2.3. Monitoring devices | | |
| Monitoring devices of nonvital 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 (extracorporal) shock-wave therapy (lithotripsy) |  |  |
| 2.5. Active (non-implantable) medical devices other than specified above | | |
| Concise specification of the purpose the medical device | Medical devices names in accordance with the scope submitted for certification | Risk classification \* |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| Technical area | Medical devices names in accordance with the scope submitted for certification | Risk classification \* |
| 3. Active Implantable Medical Devices: | | |
| 3.1. General active implantable medical device | | |
| 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 other than specified above | | |
| Concise specification of the purpose the medical device | Medical devices names in accordance with the scope submitted for certification | Risk classification \* |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| Technical area | Medical devices names in accordance with the scope submitted for certification | Risk classification \* |
| 4. In Vitro Diagnostic Medical Devices (IVD): | | |
| 4.1. Reagents and reagent products, calibrators and control materials for 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 other than specified above | | |
| Concise specification of the purpose the medical device | Medical devices names in accordance with the scope submitted for certification | Risk classification \* |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| **Technical area** | **Medical devices names in accordance with the scope submitted for certification** | |
| **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. Low-temperature steam and formaldehyde sterilization |  | |
| 5.6. Dry air thermal sterilization |  | |
| 5.7. Sterilization with hydrogen peroxide |  | |
| 5.8. Sterilization methods other than those listed above |  | |
|  | | |
| Technical area | Medical devices names in accordance with the scope submitted for certification | |
| 6. Devices incorporating/utilizing specific substances/ technologies: | | |
| 6.1. Medical devices incorporating medicinal substances |  | |
| 6.2. Medical devices utilizing tissues of animal origin |  | |
| 6.3. Medical devices incorporating derivates of human blood |  | |
| 6.4. Medical devices utilizing micromechanics |  | |
| 6.5. Medical devices utilizing nanomaterials |  | |
| 6.6. Medical devices utilizing biological active coatings and/or materials  or being wholly or mainly absorbed |  | |
| 6.7. Medical devices incorporating or utilizing specific substances/technologies/elements, other than specified above | | |
| Concise specification of the purpose the medical device | Medical devices names in accordance with the scope submitted for certification | |
|  |  | |
|  |  | |
|  |  | |
|  |  | |
|  |  | |
| Technical area | Clarification of the type of parts / services in accordance with  with the scope submitted for certification | |
| The technical areas specified in 7 are used when an organization carries out related activities or manufactures parts that are not classified as finished medical devices. | | |
| 7. Parts or Services: | | |
| 7.1. Raw materials  (Raw metals, plastic, wood, ceramic) |  | |
| 7.2. Components  (Electrical components, fasteners, shaped raw materials, machined raw materials and molded plastic) |  | |
| 7.3. Subassemblies  (Electronic subassemblies mechanical subassemblies, made to drawings and/or work instructions) |  | |
| 7.4. Calibration services  (Verification/confirmation services for measuring instruments, tools or test fixtures) |  | |
| 7.5. Distribution services  (Distributors providing storage and delivery of medical devices, not acting as a ‘legal manufacturer’ for medical devices.) |  | |
| 7.6. Maintenance services  (Electrical or mechanical repair services, facility cleaning and maintenance services, uniform cleaning and testing of ESD smocks.) |  | |
| 7.7. Transportation services  (Trucking, shipping, air transportation service in general.) |  | |
| 7.8. Other services  (Consulting services related to medical devices, packaging services, etc.) |  | |

\*In accordance with Regulation (EU) 2017/745 MDR) or 2017/746 (IVDR).

***Note:*** The technical areas highlighted in gray do not fall within the scope of PCBC S.A. accreditation, if selected, please break down the expected scope of certification (in application) into the part corresponding to the accredited area and beyond the accreditation.

1. **PLEASE ANSWER THE ADDITIONAL QUESTIONS (applies to "Parts and Services" suppliers):**

|  |  |  |
| --- | --- | --- |
| Questions: | YES | NO |
| Is the device a nearly finished and assembled medical device (i.e., it is intended for medical use and requires only packaging and/or labeling)? |  |  |
| Is the device intended to be a component/part of a medical device? |  |  |
| Has the organization been contracted to perform any activities regulated by the Medical Device Regulation (e.g., re-labeling, remanufacturing of other medical devices)? |  |  |
| Is the supplied device sterile? |  |  |
| Does the device contain software developed by the customer organization or supplier? |  |  |
| Does the scope of ISO 13485 certification include "design and development" (e.g., when public law allows exclusion of design and development, which is very often the case for low-risk medical devices)? |  |  |
| Is the product (raw materials, parts, components, subassemblies, maintenance and housekeeping services or other services) intended to support related medical devices? |  |  |

1. **CHARACTERISTICS OF PROCESSES / SUBCONTRACTING***(tick / describe* ***ALL*** *appropriate and in accordance with p. 9 of Annex 6 to IBC 01.01 (Application))*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| * 1. Does the Organization use suppliers of processes or parts that are critical to the functionality of the medical device and/or safety of user of finished products including products under its own brand:   YES  if yes, please complete the table below NO | | | | |
| **Process** | **Company / supplier name** | **Linking the supplier to your quality system / supervision mechanisms of critical suppliers (e.g. supplier audit)** | **Does the subcontractor have a certified QMS according to ISO 13485 and / or ISO 9001 for outsourced processes** | |
| **Designing** |  |  |  | |
| **Elements of the production process** |  |  |  | |
|  |  |  |  | |
|  |  |  |  | |
|  |  |  |  | |
| **packing process** |  |  |  | |
| **Sterilization** |  |  |  | |
| **Transport and storage** |  |  |  | |
| **Other** |  |  |  | |
| 4.2 Does the Organization install products at its customers:  YES  NO  **If YES, provide the scope:** | | | |

1. **CHARACTERISTICS OF LEGAL REGULATIONS** *(tick and specify main / specific for activity covered by the system)*

|  |
| --- |
| Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, ;  Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices  Other: . |

1. **DESIGN / DEVELOPMENT / PRODUCTION** *(tick / describe* ***ALL*** *appropriate)*

|  |
| --- |
| Are design, development and production carried out in branches to be certified?  YES  NO  **If YES, provide location of branch – city and processes from aforementioned which are implemented in the branch:** dd |

1. **COMBINED AUDITS** *(combined audit means system and medical device audit carried out at one time)*

|  |
| --- |
| 7.1. Does the Organization intend to apply for certification of a medical device in PCBC notified body?  NO  YES, (Note: this requires the Organization to submit a separate application to the Medical Device Certification Department)  If **YES**, whether it is to be a combined audit with a medical device audit? YES  NO  7.2. Does the Organization currently have medical device certification with a PCBC notified body?  NO  YES, in the Medical Device Certification Department.  If **YES**, is this to be a combined audit with a medical device audit YES  NO |

**8.**  **APPLICATION REVIEW – TO BY FILLED IN BY THE PCBC**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | PCBC | BCO |  |  |  |   no. month year |