**Dear Sir or Madam,**

We request to fill this proposal application which is dictated by the requirements for the certification bodies in PN-EN ISO/IEC 17021-1 standard. It will allow us to prepare the best offer for your organization.

This Application can be submitted in electronic or paper form.

After the verification of the Application, the ICR Polska Sp. z o. o. will send you an offer in maximum 3 days for conducting the certification process of the requested management system.

Also, we inform that Certification Programs for Management Systems Quality, including the Quality of Medical Devices are available on the ICR Polska Sp. z o. o. website <www.icrpolska.com>

**Information contained in this application is treated by ICR Polska Sp. z o.o. as confidential.**

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| --- | --- | --- | --- |
| **I. BASIC INFORMATION ABOUT THE APPLICANT** | | | |
| Name of the organization |  | | |
| VAT number/ Company registration number |  | | |
| Address  *(Headquarters / postcode, street, town, province)* |  | | |
| President / Director / Owner |  | | |
| Representative / Proxy  (Name and surname, phone, email) |  | | |
| **II. STAGE OF ASSESSMENT PROCESS/CERTIFICATION REQUIREMENTS** | | | |
| Initial certification | Surveillance | | Renewal of certification |
| Resumption of certification | |  | |
| ISO 13485:2016 (PN-EN ISO 13485:2016-04) | |  | |
| Exclusions  (Concerns the possibilities provided for in the standards) | |  | |

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| **III. DESIGN AND IMPLEMENTATION OF THE MANAGEMENT SYSTEM** | | | |
| By own forces | | | |
| Consulting company  (Name / Name of Consultant for last 2 years) |  | | |
| **IV. PROCESSES IDENTIFIED IN THE MANAGEMENT SYSTEM** | | | |
| The number of main processes (processes directly related to products or activities when each error affects compliance with the purpose of normative documents) |  | | |
| Number of supporting processes / auxiliary (processes that have no direct impact on compliance with the purpose of normative documents) |  | | |
| Number and types of production lines (if applicable) |  | | |
| Sub-contracted processes (please list these processes and locations according to the note in Chapter XIII of the application) |  | | |
| **V. BRANCH / LOCATIONS UNDER THE CERTIFICATION SCOPE** | | | |
| *(Please list the branches and their locations and the number of staff in each unit)* | | | |
|  | | | |
| **Responsibility for the quality management system and central supervision of the system**  **(CENTRAL FUNCTION)** | | | |
| The management system of all branches is subject to a centralized review of the Applicant's management | |  | |
| All branches are subject to the Applicant's internal audit program | |  | |
| Maintaining central system supervision includes responsibility for ensuring the collection and analysis of data from all branches | | |  |
| **VI. EMPLOYMENT** | | | |
| 1. **Total number of permanent staff involved in certification scope**   *(This number should include the permanent staff of the Applicant, including part-time staff and non-working staff, e.g. subcontractor staff working at the applicant's headquarters).*  *(The total number of permanent staff should be calculated on the equivalent of full-time staff, for example 30 people working 4 hours a day is equivalent to 15 full-time workers)* | |  | |
| **2. The number of staff employed on the contract for the work, the contract of commission** | |  | |
| **3. Number of staff** *(in the total number of permanent staff specified*  *Above), which performs functions considered as repetitive e.g. personnel*  *Cleaning, security and transport staff, merchants, tape staff, working on assembly lines)* | |  | |
| **4. Number of changes / number of production lines** | |  | |
| **5. Number of staff employed on each shift** | |  | |

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| **VII. ACTIVITY SCOPE COVERED BY CERTIFICATION** | | | | | | | | | | |
|  | | | | | | | | | | |
| **VIII. OWNING CERTIFICATES OF THE MANAGEMENT SYSTEM** | | | | | | | | | | |
| Please, list the name of the certification document by whom it was issued and the expiry date, and if you request to transfer certification from another accredited unit, include a copy of your certificate (in case of the certification in accordance with the ISO 13485 standard, it is necessary to exchange the possessed certificates of the product quality management system with the scope and certificates of compliance with regard to their medical devices) | | | | |  | | | | | |
| **IX. FACTORS RELATED TO ACTIVITIES AND MANAGEMENT SYSTEMS** | | | | | | | | | | |
| Logistics covering more than one building | | | | | | | | | |  |
| Staff speaking more than one language / necessary translator | | | | | | | | | |  |
| Wide area compared to the number of staff | | | | | | | | | |  |
| Many legal regulations, resulting from the diversity of activities | | | | | | | | | |  |
| A system with very complicated processes / relatively large number of untypical activities | | | | | | | | | |  |
| Activities that require visiting temporary departments to confirm the activities of a permanent branch which management system is subject to certification | | | | | | | | | |  |
| Very small area in relation to the number of employees (e.g. only office complex) | | | | | | | | | |  |
| Earlier certification by ICR Polska (e.g. with respect to another standard) | | | | | | | | | |  |
| Maturity of management system | | | | | | | | | |  |
| Earlier certification in another accredited unit | | | | | | | | | |  |
| Processes related to one general activity (e.g., only services) | | | | | | | | | |  |
| Identical actions performed on all shifts with appropriate evidence of equal performance across all changes based on earlier internal audits and certification bodies | | | | | | | | | |  |
| **X. TECHNICAL AREAS OF MEDICAL DEVICES**  mark only in case of applying for ISO 13485:2016 certification (PN-EN ISO 13485:2016-04) | | | | | | | | | | |
| **Main Technical Areas**  **(IAF MD 9)** | **Check box** | | | **Technical Areas** | | | | | | |
| Non-active Medical Devices |  | | | General non-active, nonimplantable medical devices | | | | | | |
|  | | | Non-active implants | | | | | | |
|  | | | Devices for wound care | | | | | | |
|  | | | Non-active dental devices and accessories | | | | | | |
|  | | | Non-active medical devices other than specified above | | | | | | |
| Active Medical Devices (NonImplantable) |  | | | General active medical devices | | | | | | |
|  | | | Devices for imaging | | | | | | |
|  | | | Monitoring devices | | | | | | |
|  | | | Devices for radiation therapy and thermo therapy | | | | | | |
|  | | | Active (non-implantable) medical devices other than specified above | | | | | | |
| Active Implantable Medical Devices |  | | | General active implantable medical devices | | | | | | |
|  | | | Implantable medical devices other than specified above | | | | | | |
| In Vitro Diagnostic Medical Devices (IVD) |  | | | Reagents and reagent products, calibrators and control materials for: Clinical Chemistry Immunochemistry (Immunology) Haematology/Haemostasis/ Immunohematology Microbiology Infectious Immunology Histology/Cytology Genetic Testing | | | | | | |
|  | | | In Vitro Diagnostic Instruments and software | | | | | | |
|  | | | IVD medical devices other than specified above | | | | | | |
| Sterilization Method for Medical Devices |  | | | Ethylene oxide gas sterilization (EOG) | | | | | | |
|  | | | Moist heat | | | | | | |
|  | | | Aseptic processing | | | | | | |
|  | | | Radiation sterilization (e.g. gamma, x-ray, electron beam) | | | | | | |
|  | | | Sterilization method other than specified above | | | | | | |
| Parts or services |  | | | Raw materials | | | | | | |
|  | | | Components | | | | | | |
|  | | | Subassemblies | | | | | | |
|  | | | Calibration services (It is recommended that organizations providing calibration services be accredited in accordance with ISO / IEC 17025) | | | | | | |
|  | | | Distribution services | | | | | | |
|  | | | Maintenance services and keeping order | | | | | | |
|  | | | Transportation services | | | | | | |
|  | | | Other services | | | | | | |
| Devices incorporating/utilizing specific substances/ technologies |  | | | Medical devices incorporating medicinal substances | | | | | | |
|  | | | Medical devices utilizing tissues of animal origin | | | | | | |
|  | | | Medical devices incorporating derivates of human blood | | | | | | |
|  | | | Medical devices utilizing micromechanics | | | | | | |
|  | | | Medical devices utilizing nanomaterials | | | | | | |
|  | | | Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed | | | | | | |
|  | | | Medical devices incorporating or utilizing specific substances/technologies/elements, other than specified above. | | | | | | |
| **Warning:**  When selecting the ***Main technical areas*** listed above in chapter XII  (**with the exception of the** ***Parts and services*** **area**) it should be remembered that they concern ready-made medical devices.  A finished medical device is defined as any medical device or equipment of any medical device that is either usable or able to function, regardless of whether it has been packaged, labeled (- e) or subjected to sterilization. | | | | | | | | | | |
| **XI.** **FACTORS RELATED TO ACTIVITIES AND QUALITY MANAGEMENT SYSTEM OF MEDICAL DEVICES** | | | | | | | | | | |
| The scope of the organization does not include production but only activities such as wholesale, retail, transport or maintenance of the equipment *(if so, please also refer to the appropriate scope from the above)* | | | | | | | | |  | |
| The scope of certification covers only "distribution services" or "transport services"(chapter XII of the application) | | | | | | | | |  | |
| There is an activity in the organization related to products that do not have medical or therapeutic uses (so-called borderline products such as cosmetics, herbal products, dietary supplements, cosmetic salon equipment, etc.) or not directly related to prevention or restoration of human health. | | | | | | | | |  | |
| Design and development is carried out in branches | | | | | | | | |  | |
| Production is carried out in branches | | | | | | | | |  | |
| Number of produced assortment | | | | | | | | |  | |
| The organization uses suppliers of processes or parts that are critical to the functionality of the medical device and / or the safety of the user of finished products, including self-branded products (if so please specify the scope of subcontracting in Chapter V of this application). | | | | | | | | |  | |
| The organization as a manufacturer installs products at the customer's location (if so, please list them). | | | | | | | | |  | |
| There has been a reduction in the scope of the manufacturer's products since the last audit  (If so please change the scope) | | | | | | | | |  | |
| Design / / production limitation has occurred since the last audit (If so please change range) | | | | | | | | |  | |
| **XII. STATUTORY REQUIREMENTS AND PROVISIONS APPLICABLE TO SAFETY AND ACTIVITIES OF MEDICAL DEVICES (please list below)** | | | | | | | | | | |
|  | | | | | | | | | | |
| **XIII. PLANNED DATE OF BEING READY FOR CERTIFICATION OR COMMUNICATION** | | | | | | | | | | |
| Suggested date  (Please indicate the date of being ready for evaluation by ICR Polska Sp. Z o.o.- week / month) | | | | | |  | | | | |
| Language of the audit | | polish | | | | english | | *other (which)* | | |
| Language of the audit report | | polish | | | | english | | *other (which)* | | |
| **XIV. SOURCES OF SERVICE INFORMATION OF ICR Polska Sp. z o. o.** | | | | | | | | | | |
| Trainings | | Individual contact | | | | | Fairs | Internet | | |
| Commercial materials  of ICR Polska Sp. z. o. o. | | Press advertising | | | | | | Other | | |
| *We agree to the collection, storage, processing, transfer, sharing and using of received data in the process of management system certification conducted by ICR Polska Sp. z o. o. in accordance with the Personal Data Protection Act (Marshal Notice Parliament of the Republic of Poland of 25 November 2015 on the publication of uniform text of the Act about the protection of personal data - Dz. U 2015 pos. 2135* | | | | | | | | | | |
| **XV. PERSON AUTHORIZED BY THE APPLICANT** | | | | | | | | | | |
| Name and surname | | |  | | | | | | | |
| Position/phone/e-mail | | |  | | | | | | | |
| Date and signature | | |  | | | | | | | |