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| **Codes (MDR 2017/745 and MDD 93/42 EEC NANDO Codes)** | **Please provide relevant experience for the MDR 2017/745 and MDD 93/42 EEC NANDO Codes below- include the amount of years of experience in the particular code, including QMS and design experience.** **If the applicant has experience with another Notified body please provide a log of audits performed per code.**  |
| **MDA 0101****Active implantable devices for stimulation inhibition monitoring****AIMD0101** | **Example of Experience** **Specific experience in the required area**Primary experience from working for: PacersRUs Quality Manager for Implantable Cardiac Pacemakers and Defibrillators (2 years)Responsible for compliance program, complaint handling, return productanalysis(testing) Regulatory, Quality Systems and compliance• Conduct Internal audits to US FDA 21CFR 820, EN ISO 13485, AIMD and MDSAP.• Providing response to Notified Bodyfindings including system implementation; revision of applicable documentation (procedures, reports)..**Audit Log for specific code**  |
| **MDA 0102****Active implantable devices delivering drugs or other substances****AIMD0101** |  |
| **MDA 0201****Active non-implantable imaging devices utilising ionizing radiation****MD 1201** |  |
| **MDA 0202****Active non-implantable imaging devices utilising non-ionizing radiation****MD 1202** |  |
| **MDA 0203****Active non-implantable devices for monitoring of vital physiological parameters****MD 1302** |  |
| **MDA 0204****Other active non-implantable devices for monitoring and/or diagnosis****MD 1301** |  |
| **MDA 0301****Active non-implantable devices utilising ionizing radiation****MD 1401** |  |
| **MDA 0302****Active non-implantable devices utilising non-ionizing radiation****MD 1402** |  |
| **MDA 0303****Active non-implantable devices utilising hyperthermia / hypothermia****MD 1403** |  |
| **MDA 0304****Active non-implantable devices for shock-wave therapy (lithotripsy)****MD 1404** |  |
| **MDA 0305****Active non-implantable devices for stimulation or inhibition****MD 1103** |  |
| **MDA 0306****Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemopheresis****MD 1101** |  |
| **MDA 0307****Active non-implantable respiratory devices****MD 1102** |  |
| **MDA 0308****Active non-implantable devices for wound and skin care** |  |
| **MDA 0309****Active non-implantable ophthalmologic devices****MD 1105** |  |
| **MDA 0310****Active non-implantable devices for ear, nose and throat** |  |
| **MDA 0311****Active non-implantable dental devices****MD 1106** |  |
| **MDA 0312****Other active non-implantable surgical devices****MD 1104** |  |
| **MDA 0313****Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport****MD 1108 & MD 1109** |  |
| **MDA 0315****Standalone software****MD 1111** |  |
| **MDA 0317****Active non-implantable devices for cleaning, disinfection and sterilisation****MD 1107** |  |
| **MDA 0318****Other active non-implantable devices** |  |
| **MDN 1101****Non-active cardiovascular, vascular and neurovascular implants****MD 0201** |  |
| **MDN 1102****Non-active osteo- and orthopaedic implants****MD 0202** |  |
| **MDN 1103****Non-active dental implants and dental materials****MD 0403** |  |
| **MDN 1104****Non-active soft tissue and other implants****MD 0203/0204** |  |
| **MDN 1200 Series****MDSAP Only** |  |
| **MDN 1201****Non-active non-implantable devices for anaesthesia, emergency and intensive care****MD 0101** |  |
| **MDN 1202****Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis****MD 0102** |  |
| **MDN 1203****Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools** |  |
| **MDN 1204****Non-active non-implantable devices for wound and skin care****MD 0301-MD 0303** |  |
| **MDN 1205****Non-active non-implantable orthopaedic and rehabilitation devices****MD 0103** |  |
| **MDN 1206****Non-active non-implantable ophthalmologic devices****MD 0105** |  |
| **MDN 1207****Non-active non-implantable diagnostic devices** |  |
| **MDN 1208****Non-active non-implantable instruments** |  |
| **MDN 1209****Non-active non-implantable dental materials****MD 0401/0402** |  |
| **MDN 1210****Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases****MD 0107** |  |
| **MDN 1211****Non-active non-implantable devices for disinfecting, cleaning and rinsing****MD 0108** |  |
| **MDN 1212****Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)****MD 0109** |  |
| **MDN 1213****Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route** |  |
| **MDN 1214****General non-active non-implantable devices used in health care and other non-active non-implantable devices** |  |

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| **Devices with specific characteristics**  | **Please provide relevant experience for the MDR 2017/745 and MDD 93/42 EEC NANDO Codes below- include the amount of years of experience in the particular code, including QMS and design experience.** **If the applicant has experience with another Notified body please provide a log of audits performed per code.** |
| **MDS 1001****Devices incorporating medicinal substances****MDS 7001** |  |
| **MDS 1002****Devices manufactured utilising tissues or cells of animal origin, or their derivatives****MDS 7002** |  |
| **MDS 1003****Devices manufactured utilising tissues or cells of human origin, or their derivatives****MDS 7003** |  |
| **MDS 1004****Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council****MDS 7004** |  |
| **MDS 1005****Devices in sterile condition****MDS 7006** |  |
| **MDS 1005E****Devices in sterile condition-ETO** |  |
| **MDS 1005MH****Devices in sterile condition-Moist Heat** |  |
| **MDS 1005A****Devices in sterile condition-Aseptic** |  |
| **MDS 1005C****Devices in sterile condition-Chemical** |  |
| **MDS 1005R****Devices in sterile condition-Irradiation**  |  |
| **MDS 1006****Reusable surgical instruments** |  |
| **MDS 1008****Devices utilising biological active coatings and / or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body****MDS 7009** |  |
| **MDS 1009****Devices incorporating software / utilising software / controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices****MDS 7010** |  |
| **MDS 1010****Devices with a measuring function****MD 0104** |   |
| **MDS 1011****Devices in systems or procedure packs** |  |
| **MDS 1012****Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745** |  |
| **MDS 1014****Devices incorporating as an integral part an in vitro diagnostic devices** |  |