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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 product  analysis(testing)  Regulatory, Quality Systems and compliance  • Conduct Internal audits to US FDA 21  CFR 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** |  |