

2 Roles ³

- Site auditor (SA)** **Lead auditor (LA)** **Project leader (PL)**
 Product reviewer (PR). If the product reviewer is responsible only for a specific non-code related area (e.g. testing, biological safety), please indicate the relevant area:

 Internal clinician (IC) **Clinical specialist (CS)**
 Final reviewer (FR) **Decision maker (DM)**

Reference to the conformity assessment body's competence criteria used for the purpose of this authorisation (i.e. document reference and version) including criteria for maintaining competence, and process of selection and authorisation of personnel: _____

3 Relevant education

No	Date of completion and duration	Technical college / university	Relevant subject(s)	Type/level of qualification and official name of the qualification granted
3.1				
3.2				
3.3				
3.4				

Comments:

4 Relevant working experience

No	from - to	Employer	Department / position	Responsibilities with respect to design, manufacture, testing or use of device or technologies or experience in a conformity assessment body (please indicate the codes involved in each task) ⁴
4.1				
4.2				
4.3				

³ Additional roles defined by the applicant CAB should be added to this table.
⁴ In case the number of QMS audits or technical file reviews carried out are part of the competence criteria established by the notified body (e.g. minimum 40 hours CE certification audit) a reference should be provided to the specific manufacturer, role performed by the expert and relevant codes involved. When the experience has been acquired internally, the notified body should make the relevant log available upon request. When acquired externally statements / logs from the former employers should be made available.

4.4				
4.5				
4.6				
4.7				
4.8				
4.9				

Comments:

5 Training and professional development

No	Date of completion and number of days / hours	Name of the training provider / company / organisation / university providing the training, if applicable ⁵	Title of the training and appropriate description of topics covered	Certificate granted, if any
5.1				
5.2				
5.3				
5.4				
5.5				
5.6				
5.7				
5.8				
5.9				

Comments:

6 Other relevant experience

⁵ It is expected that this information will always be given except in the case of self-training.



7 Authorisation to roles / functions and codes and rationale for this authorisation including reference to information given in sections 3-6

Codes	Roles ⁶ acc.to sec. 2	Limitations per role ⁷	Reference to sections 3 to 6	Rationale per role for the initial authorisation and/or the maintenance / limitation of the authorisation justification in case that the combination of reference in the previous column is not self- explanatory or in case of derogations from the CAB competence criteria.
MDA 0101 Active implantable devices for stimulation / inhibition / monitoring	SA			
	PR			
	IC			
	CS			
	FR			
	DM			
MDA 0102 Active implantable devices delivering drugs or other substances				
MDA 0103 Active implantable devices substituting or replacing organ functions				
MDA 0104 Active implantable devices utilising radiation and other active implantable devices				
MDA 0201 Active non-implantable imaging devices utilising ionizing radiation				
MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation				
MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters				
MDA 0204 Other active non- implantable devices for monitoring and/or diagnosis				
MDA 0301 Active non-implantable devices utilising ionizing radiation				

⁶ As many lines as roles included in the scope of authorisation of the person should be included as per the example given for code MDA 0101.

⁷ When a product reviewer is authorised only for a specific non –code related area, or in case the person's authorisation is limited to a specific area (e.g. clinical experts) such area should also be indicated in this column.

MDA 0302 Active non-implantable devices utilising non-ionizing radiation				
MDA 0303 Active non-implantable devices utilising hyperthermia / hypothermia				
MDA 0304 Active non-implantable devices for shock-wave therapy (lithotripsy)				
MDA 0305 Active non-implantable devices for stimulation or inhibition				
MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis				
MDA 0307 Active non-implantable respiratory devices				
MDA 0308 Active non-implantable devices for wound and skin care				
MDA 0309 Active non-implantable ophthalmologic devices				
MDA 0310 Active non-implantable devices for ear, nose and throat				
MDA 0311 Active non-implantable dental devices				
MDA 0312 Other active non-implantable surgical devices				
MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport				

MDA 0314 Active non-implantable devices for processing and preservation of human cells, tissues or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)				
MDA 0315 Software				
MDA 0316 Medical gas supply systems and parts thereof				
MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation				
MDA 0318 Other active non-implantable devices				
MDN 1101 Non-active cardiovascular, vascular and neurovascular implants				
MDN 1102 Non-active osteo- and orthopaedic implants				
MDN 1103 Non-active dental implants and dental materials				
MDN 1104 Non-active soft tissue and other implants				
MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care				
MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis				
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				

MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices				
MDN 1206 Non-active non-implantable ophthalmologic devices				
MDN 1207 Non-active non-implantable diagnostic devices				
MDN 1208 Non-active non-implantable instruments				
MDN 1209 Non-active non-implantable dental materials				
MDN 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases				
MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing				
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)				
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				
MDS 1001 Devices incorporating medicinal substances				
MDS 1002 Devices manufactured utilising tissues or cells of human origin, or their derivatives				

MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives				
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 1005 Devices in sterile condition				
MDS 1006 Reusable surgical instruments				
MDS 1007 Devices incorporating or consisting of nanomaterial				
MDS 1008 Devices utilising biologically 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 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 1010 Devices with a measuring function				
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 1013 Class III custom-made implantable devices				
MDS 1014 Devices incorporating as an integral part an <i>in vitro</i> diagnostic device				

MDT 2001 Devices manufactured using metal processing				
MDT 2002 Devices manufactured using plastic processing				
MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)				
MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)				
MDT 2005 Devices manufactured using biotechnology				
MDT 2006 Devices manufactured using chemical processing				
MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals				
MDT 2008 Devices manufactured in clean rooms and associated controlled environments				
MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin				
MDT 2010 Devices manufactured using electronic components including communication devices				
MDT 2011 Devices which require packaging, including labelling				
MDT 2012 Devices which require installation, refurbishment				
MDT 2013 Devices which have undergone reprocessing				

For completeness and correctness

date

Personnel signature

For granting of authorisation

date

Personnel responsible for autorisation signature