







Status of The Application Process for MDR

This result is based on 35 responses.



What is the status of your application process?

		Answers	Ratio
Application not submitted, yet. No decision made.		1	2.86%
Application submitted	■	2	5.71%
Application intended to be submitted this year	■■■■■■■■■■■■■■■■■■■■	16	45.71%
Application intended to be submitted next year or later		1	2.86%
Application completeness confirmed by CA	■	3	8.57%
Document check finished by CA		1	2.86%
Joint Assessment scheduled	■■	5	14.29%
Joint Assessment performed	■■■■	6	17.14%
Joint Assessment closed		0	0%
Divergent Opinion still open		0	0%
National Designation Decision available		0	0%
No Answer		0	0%







If your Joint Assessment is schedule, what month will be/was the assesement?

		Answers	Ratio
1		0	0%
2		0	0%
3		0	0%
4		4	11.43%
5		0	0%
6		3	8.57%
7		0	0%
8		0	0%
9		2	5.71%
10		1	2.86%
11		1	2.86%
12		0	0%
No Answer		24	68.57%





If your Joint Assessment is schedule, what year will be/was the assesement?

		Answers	Ratio
2018		11	31.43%
2019		0	0%
2020		0	0%
No Answer		24	68.57%







How many FTE do you employ (including corporation):

		Answers	Ratio
up to 50		20	57.14%
up to 100		8	22.86%
upto 200		2	5.71%
up to 400		1	2.86%
up to 600		0	0%
more than 600		3	8.57%
No Answer		1	2.86%





How many subcontractors do you use for the conformity assessment?

		Answers	Ratio
up to 10		15	42.86%
up to 50		14	40%
up to 100		2	5.71%
up to 200		0	0%
No Answer		4	11.43%




How many certificates (MDD + AIMD) are currently valid?

		Answers	Ratio
up to 250		16	45.71%
up to 500		9	25.71%
up to 1.000		5	14.29%
up to 1.50		0	0%
up to 2.500		1	2.86%
More than 2.500		3	8.57%
No Answer		1	2.86%






Does the scope you applied for equals the existing scope mentioned in NANDO as of today?

		Answers	Ratio
Yes		15	42.86%
No, because we applied for a broader scope		16	45.71%
No, because we applied for a smaller scope		3	8.57%
No Answer		1	2.86%



What product groups are covered by your applicaiton?




		Answers	Ratio
Active Devices		31	88.57%
Non-active Devices		32	91.43%
No Answer		1	2.86%

MDA 0100: Active implantable devices for stimulation / inhibition / monitoring









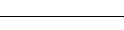
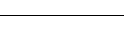




		Answers	Ratio
MDA 0101: Active implantable devices for stimulation / inhibition / monitoring		14	40%
MDA 0102: Active implantable devices delivering drugs or other substances		11	31.43%
MDA 0103: Active implantable devices supporting or replacing organ functions		9	25.71%
MDA 0104: Active implantable devices utilising radiation and other active implantable devices		10	28.57%
No Answer		21	60%






MDA 0200: Active non-implantable devices for imaging, monitoring and / or diagnosis

		Answers	Ratio
MDA 0201: Active non-implantable imaging devices utilising ionizing radiation		21	60%
MDA 0202: Active non-implantable imaging devices utilising non-ionizing radiation		24	68.57%






MDA 0203: Active non-implantable devices for monitoring of vital physiological parameters		26	74.29%
MDA 0204: Other active non-implantable devices for monitoring and / or diagnosis		26	74.29%
No Answer		9	25.71%

MDA 0300: Active non-implantable therapeutic devices and general active non-implantable devices








		Answers	Ratio
MDA 0301: Active non-implantable devices utilising ionizing radiation		22	62.86%
MDA 0302: Active non-implantable devices utilising non-ionizing radiation		24	68.57%
MDA 0303: Active non-implantable devices utilising hyperthermia / hypothermia		21	60%
MDA 0304: Active non-implantable devices for shock-wave therapy (lithotripsy)		17	48.57%
MDA 0305: Active non-implantable devices for stimulation or inhibition		24	68.57%
MDA 0306: Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis		24	68.57%
MDA 0307: Active non-implantable respiratory devices		25	71.43%
MDA 0308: Active non-implantable devices for wound and skin care		24	68.57%
MDA 0309: Active non-implantable ophthalmologic devices		23	65.71%
MDA 0310: Active non-implantable devices for ear, nose and throat		23	65.71%
MDA 0311: Active non-implantable dental devices		25	71.43%
MDA 0312: Other active non-implantable surgical devices		26	74.29%
MDA 0313: Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport		22	62.86%
MDA 0314: Active non-implantable devices for processing a. preservation of human cells, tissues or organs including (IVF) and (ART)		12	34.29%









MDA 0315: Software		27	77.14%
MDA 0316: Medical gas supply systems and parts thereof		22	62.86%
MDA 0317: Active non-implantable devices for cleaning, disinfection and sterilisation		22	62.86%
MDA 0318: Other active non-implantable devices		24	68.57%
No Answer		6	17.14%

MDN 0100: Non-active implants and long term surgically invasive devices



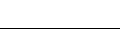







		Answers	Ratio
MDN 1101: non-active cardiovascular, vascular and neurovascular implants		25	71.43%
MDN 1102: Non-active osteo- and orthopaedic implants		30	85.71%
MDN 1103: Non-active dental implants and dental materials		31	88.57%
MDN 1104: Non-active soft tissue and other implants		30	85.71%
No Answer		4	11.43%






MDN 01200: Non-active non-implantable devices

		Answers	Ratio
MDN 1201: Non-active non-implantable devices for anaesthesia, emergency and intensive care		29	82.86%
MDN 1202: Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis		27	77.14%
MDN 1203: Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools		27	77.14%
MDN 1204: Non-active non-implantable devices for wound and skin care		30	85.71%
MDN 1205: Non-active non-implantable orthopaedic and rehabilitation devices		27	77.14%
MDN 1206: Non-active non-implantable ophthalmologic devices		27	77.14%
MDN 1207: Non-active non-implantable diagnostic devices		27	77.14%















MDN 1208: Non-active non-implantable instruments		30	85.71%
MDN 1209: Non-active non-implantable dental materials		29	82.86%
MDN 1210: Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases		22	62.86%
MDN 1211: Non-active non-implantable devices for disinfecting, cleaning and rinsing		30	85.71%
MDN 1212: Non-active non-implantable devices for processing and pre- preservation of human cells, tissue or organs including (IVF) and (ART)		14	40%
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		28	80%
MDN 1214: General non-active non-implantable devices used in health care and other non-active non-implantable devices		29	82.86%
No Answer		5	14.29%

MDS 1000: Devices with specific characteristics





		Answers	Ratio
MDS 1001: Devices incorporating medicinal substances		26	74.29%
MDS 1002: Devices manufactured utilising tissues or cells of human origin, or their derivatives		8	22.86%
MDS 1003: Devices manufactured utilising tissues or cells of animal origin, or their derivatives		20	57.14%
MDS 1004: Devices which are also machinery as defined in point (a) ... Article 2 of Directive 2006/42/EC ...		28	80%
MDS 1005: Devices in sterile condition		31	88.57%
MDS 1006: Reusable surgical instruments		27	77.14%
MDS 1007: Devices incorporating or consisting of nanomaterial		17	48.57%
MDS 1008: Devices utilising biologically active coatings ... or are intended to undergo a chemical change in the body		28	80%
MDS 1009: Devices incorporating software ... including ... influencing the performance of active or active implantable devices		29	82.86%
MDS 1010: Devices with a measuring function		32	91.43%

MDS 1011: Devices in systems or procedure packs		30	85.71%
MDS 1012: Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745		26	74.29%
MDS 1013: Class III custom-made implantable devices		19	54.29%
MDS 1014: Devices incorporating as an integral part an in vitro diagnostic device		21	60%
No Answer		3	8.57%





MDT 2000: Devices for which specific technologies or processes are used

		Answers	Ratio
MDT 2001: Devices manufactured using metal processing		31	88.57%
MDT 2002: Devices manufactured using plastic processing		32	91.43%
MDT 2003: Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)		31	88.57%
MDT 2004: Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)		31	88.57%
MDT 2005: Devices manufactured using biotechnology		30	85.71%
MDT 2006: Devices manufactured using chemical processing		31	88.57%
MDT 2007: Devices which require knowledge regarding the production of pharmaceuticals		28	80%
MDT 2008: Devices manufactured in clean rooms and associated controlled environments		31	88.57%
MDT 2009: Devices manufactured using processing of materials of human, animal, or microbial origin		22	62.86%
MDT 2010: Devices manufactured using electronic components including communication devices		28	80%
MDT 2011: Devices which require packaging, including labelling		32	91.43%
MDT 2012: Devices which require installation, refurbishment		27	77.14%
MDT 2013: Devices which have undergone reprocessing		19	54.29%
No Answer		3	8.57%

Please mark special CAP you plan to provide:

		Answers	Ratio
Article 16 (OEM, PLM)		27	77.14%
Article 17 (Reprocessing single-use devices)		9	25.71%
Annex XVI (devices w/o medical purpose)		24	68.57%
No Answer		1	2.86%

Do you plan to accept applications for reusable surgical instruments?

		Answers	Ratio
Yes		22	62.86%
No		2	5.71%
Not decided, yet		8	22.86%
No Answer		3	8.57%