



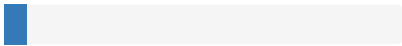

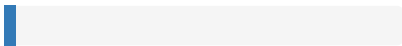
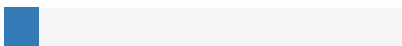
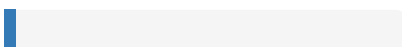
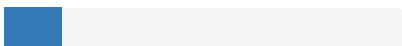
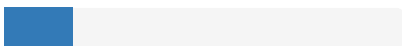
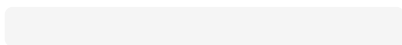
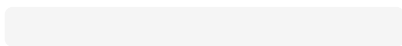
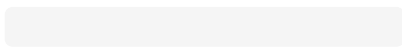
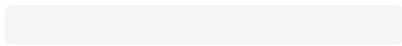


Statistics: Increasing Transparency of Designation Process

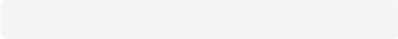
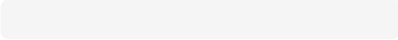
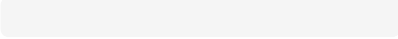
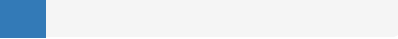
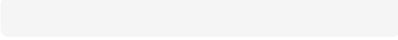
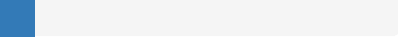
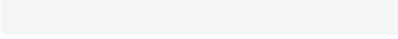
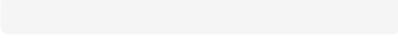
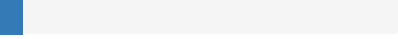
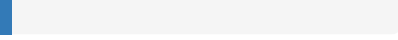
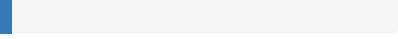
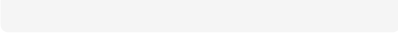

Are you member of Team-NB?

		Answers	Ratio
Yes		17	48.57 %
No		18	51.43 %
No Answer		0	0 %

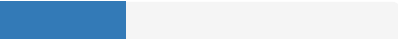
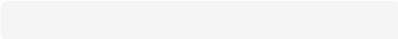
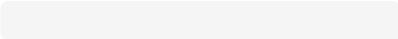

What is the status of your application process?

		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 assessement?

		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 assessement?

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





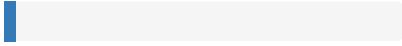
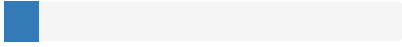
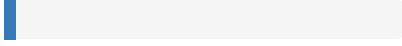
How many FTE do you employ (including corporation):

		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 %

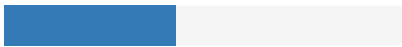

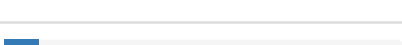

How many subcontractors do you use for the conformity assessment?

		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 %



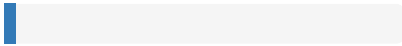
How many certificates (MDD + AIMD) are currently valid?

		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 %

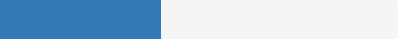
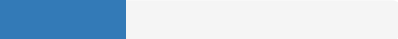
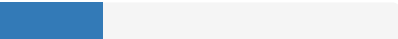
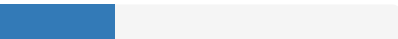

Does the scope you applied for equals the existing scope mentioned in NANDO as of today?

		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 %





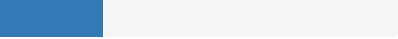
What product groups are covered by your applicaiton?

		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












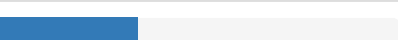



		Answers	Ratio
MDA 0101: Active implantable devices for stimulation / inhibition / monitoring		14	40 %
MDA 0102: Active implantable devices delivering drugs or other substances		11	31.43 %
MDA 0103: Active implantable devices supporting or replacing organ functions		9	25.71 %
MDA 0104: Active implantable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


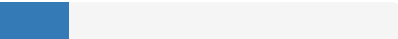
MDA 0200: Active non-implantable devices for imaging, monitoring and / or diagnosis

		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 %





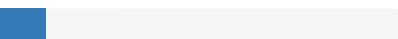
MDA 0300: Active non-implantable therapeutic devices and general active non-implantable devices

		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 %






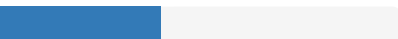


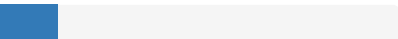
MDA 0318: Other active non-implantable devices		24	68.57 %
No Answer		6	17.14 %

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


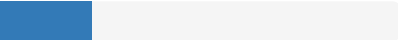












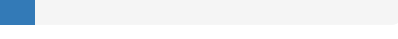
		Answers	Ratio
MDN 1101: non-active cardiovascular, vascular and neurovascular implants		25	71.43 %
MDN 1102: Non-active osteo- and orthopaedic implants		30	85.71 %
MDN 1103: Non-active dental implants and dental materials		31	88.57 %
MDN 1104: Non-active soft tissue and other implants		30	85.71 %
No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

MDN 01200: Non-active non-implantable devices














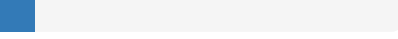
		Answers	Ratio
MDN 1201: Non-active non-implantable devices for anaesthesia, emergency and intensive care		29	82.86 %
MDN 1202: Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis		27	77.14 %
MDN 1203: Non-active non-implantable 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 %


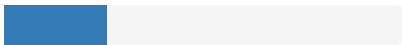

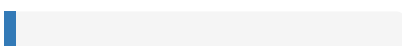
MDS 1000: Devices with specific characteristics

		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 %


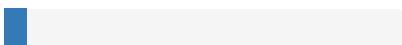
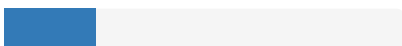
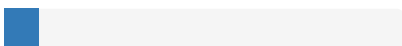
MDT 2000: Devices for which specific technologies or processes are used

		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 %