Digimed Medizintechnik Patrick Mohr
Kreutzerstraße 1
78573 Wurmlingen
Germany

Notified Body Confirmation Letter

Registration no.: D1478100004

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that mdc medical device certification GmbH (Kriegerstr. 6, 70191 Stuttgart, Germany), a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0483 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Digimed Medizintechnik Patrick Mohr
Kreutzerstraße 1
78573 Wurmlingen
Germany
SRN: DE-MF-000007328

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which a MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which a MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by 20 March 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by Regulation (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Stuttgart, 2024-09-06

Head of Notified Body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Bone plates CMF system **4058544000002723C**	Class IIb implantable WET device	N/A	MDD certificate: D1478100002, NB#0483 Expiry date: 2024-05-26
Bone screws CMF system **4058544000002733E**	Class IIb implantable WET device	N/A	MDD certificate: D1478100002, NB#0483 Expiry date: 2024-05-26
Meshes CMF system **4058544000002743G**	Class IIb implantable WET device	N/A	MDD certificate: D1478100002, NB#0483 Expiry date: 2024-05-26
Bone plates **4058544000002773N**	Class IIb implantable WET device	N/A	MDD certificate: D1478100002, NB#0483 Expiry date: 2024-05-26
Bone screws **4058544000002763L**	Class IIb implantable WET device	N/A	MDD certificate: D1478100002, NB#0483 Expiry date: 2024-05-26
Cannulated screws **4058544000002753J**	Class IIb implantable WET device	N/A	MDD certificate: D1478100002, NB#0483 Expiry date: 2024-05-26

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
01 General surgical scissors **4058544000000018P**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Iris scissors **4058544000000068Z**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Ear scissors **40585440000000793**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Thread scissors **40585440000000895**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Tonsil scissors **40585440000000997**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Nose scissors **4058544000000108Q**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Umbilical cord scissors **4058544000000118S**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Enucleation scissors **4058544000000128U**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Rectal scissors **4058544000000138W**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Rigid endoscopic scissors **4058544000000148Y**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Vascular scissors **40585440000001592**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
02 Micro scissors **40585440000001694**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
03 Scalpel handle **40585440000001796**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
03 Scalpel, reusable **40585440000001898**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
03 Amputation knife **4058544000000199A**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
03 Periodontal knife **4058544000000208T**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
03 Tonsil knife **4058544000000218V**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
03 Nose knife **4058544000000228X**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
03 Meniscus knife **4058544000000238Z**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
03 Throat knife **40585440000002493**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
03 Ear knife **40585440000002595**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
03 Ophthalmic knife, reusable **40585440000002697**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
03 Myoma knife **40585440000002799**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
03 Cartilage knife **4058544000000289B**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
05 Orthopaedic chisel **40585440000003292**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
05 Dental osteotome **40585440000003394**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
06 Hollow chisel pliers **40585440000003496**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
06 Nasal Rongeur **40585440000003598**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
06 Rib rongeur **4058544000000369A**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
06 Bone splinter forceps **4058544000000379C**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
07 Manual dermatome **4058544000000389E**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
08 Urethrotom **4058544000000399G**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
09 Bone punch **4058544000000408Z**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
09 Tonsil punch **40585440000004295**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
09 Biopsy punch **40585440000004397**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
10 Adenotome **40585440000004499**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
10 nasal loop, reusable **4058544000000459B**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
10 tonsil loop **4058544000000469D**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
10 ear loop **4058544000000479F**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
10 lens loop **4058544000000489H**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Surgical tweezers **4058544000000499K**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Ophthalmic tweezers **40585440000005094**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 ENT tweezers **40585440000005298**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Implant handling tweezers, **4058544000000539A**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
02 intestinal clamp **4058544000000569G**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
02 Rectal clamp **4058544000000579J**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
02 Uterine clamp **4058544000000589L**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
02 Bronchus clamp **4058544000000599N**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
02 Pyloric clamp **40585440000006097**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
02 Dissecting forceps **40585440000006199**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
02 Spermatic cord clamp **4058544000000629B**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
04 Vascular clips: **4058544000000689P**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
04 Artery clamp **4058544000000699R**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
04 Vascular clamps: **4058544000000709A**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
04 Bulldog clamp: **4058544000000719C**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
05 Surgical clamp applicator **4058544000000729E**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
07 Ear pliers **4058544000000779Q**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
07 Hammerhead pliers **4058544000000789S**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
07 Wire holding/wire bending pliers: **4058544000000799U**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
07 ENT forceps **4058544000000849M**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
07 Lung grasping forceps, self-holding **4058544000000899X**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
07 Kidney forceps, self-holding **4058544000000909G**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
07 Gallbladder forceps, self-holding **40585440000000919J**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
07 Swab forceps **4058544000000939N**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
07 Tampon forceps: **4058544000000949Q**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
07 Wire holding/wire twisting pliers **4058544000000969U**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
07 Surgical stone grasping forceps **4058544000000989Y**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
07 Surgical stone grasping forceps **405854400000099A2**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
07 Intestinal/tissue forceps **4058544000001008S**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
07 Hemorrhoid clamp, reusable **40585440000010492**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
07 Tendon forceps **40585440000010594**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
Bone forceps **40585440000010696**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
07 Rigid endoscopy forceps, reusable **4058544000001089A**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
09 Vein stripper, reusable **40585440000011393**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
09 Tendon stripper **40585440000011495**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
09 Intraluminal artery stripper, reusable **40585440000011597**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
16 Bone holding clamp **40585440000012396**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
04 Wound retractor, semi-deep/ deep **40585440000013195**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
04 Dental retractor **40585440000013297**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
04 Self-retaining surgical retractor, reusable **40585440000013399**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
04 Bone repositioning hook **4058544000001349B**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
03 Bone distraction forceps **4058544000001379H**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
04 Jawbone separator **4058544000001389K**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
05 Eye muscle hooks **4058544000001399M**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
05 Irish hook **40585440000014096**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
05 Tendon hook **40585440000014198**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
05 Fistula hook **4058544000001429A**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
05 Rectal hook **4058544000001439C**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
05 Trachea hook **4058544000001449E**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
05 ENT middle ear hook **4058544000001459G**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
05 Nerve/vascular hook **4058544000001469J**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
06 Surgical spatula **4058544000001489N**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
06 Vascular spatula **4058544000001499Q**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
06 Lung spatula **4058544000001519B**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
07 Tracheadilator **4058544000001529D**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
07 Vascular dilator **4058544000001569M**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
07 Main bile duct dilator **4058544000001579P**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 ENT elevator **4058544000001779V**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Periosteal elevator **4058544000001789X**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
01 Root elevator **4058544000001799Z**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Jawbone separator **4058544000001819L**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Manual surgical saw, rigid **4058544000002008X**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Manual surgical saw, flexible **4058544000002018Z**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Nose saw **40585440000020293**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
02 Non-sterile fluted surgical drill, reusable **4058544000002069B**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
02 Osteotomy bone cutter **4058544000002089F**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
02 Bone thread cutter, reusable **4058544000002099H**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
03 Skin punch **40585440000021092**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
03 Corneal trephine , manual instrument **40585440000021194**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
02 Awl: **40585440000021296**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Needle holder, reusable: **4058544000002199L**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
Skin sewing needle, reusable **40585440000022095**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
Wire/ ligature guide **40585440000022197**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
Thread/needle guide **40585440000022299**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
03 Suprapubic Trocar: **4058544000002289M**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
03 Orthopaedic trocar : **4058544000002299P**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
03 Gallbladder trocar **40585440000023098**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
03 Tracheal trocar **4058544000002319A**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
07 Guide hollow probes **405937500000237CB**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
11 Wire/ ligature guide **405937500000243C6**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
08 Orthopaedic wire **4058544000002389Q**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
09 Catheter insertion trocar **4058544000002399S**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Bone curette **4058544000002469P**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Intrauterine curette, manual **4058544000002479R**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Endometrial biopsy curette **4058544000002489T**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Endaural curette **4058544000002509E**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Ophthalmic curette, reusable **4058544000002519G**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Uterine spoon: **4058544000002549N**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 All-purpose curette **4058544000002559Q**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Gallstone Spoon: **4058544000002569S**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Periodontal curette **4058544000002579U**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Ear excavator: **4058544000002609H**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
02 Nasal rasp: **4058544000002629M**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
02 Bone rasp: **4058544000002639P**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
03 Dissector, general: **4058544000002669V**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
01 Excavator, dental: **4058544000002619K**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
07 Surgical drill guide, reusable **4058544000002359J**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
10 surgeon's keys **4058544000002419D**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
07 Targeting/guiding device for orthopedic implants: **4058544000002369L**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483
10 surgical screwdrivers, reusable **4058544000002409B**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives, NB#0483

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-09-06	D1478100004	Initial