

TÜV Rheinland LGA Products GmbH • 51105 Köln

Grena (Qingdao) Medical Devices Ltd.
No.318 Huanghe West Road, Huangdao District,
Qingdao City,
266555 Shandong,
P.R. China

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com
Date December 13, 2023

Notified Body Confirmation Letter

Reference. : 244545828

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 **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** 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:

Grena (Qingdao) Medical Devices Ltd.
No.318 Huanghe West Road, Huangdao District,
Qingdao City, 266555 Shandong,
P.R. China
SRN Number: CN-MF-000009861

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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 March 20, 2023 for the relevant devices.

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

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 (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 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)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 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)

On behalf of the Notified Body



Fuxiu Sheng
Certification 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
Connecting tube Basic UDI-DI: 697269668010QG Model: 0201-18007SS 0201-18007LL 0201-18007SL 0201-18007SC 0201-18007LC 0201-18007ST 0201-18007SSVS 0201-18007SSP 0201-20007SS 0201-20007LL 0201-20007SL 0201-20007SC 0201-20007LC 0201-20007ST 0201-20007SSVS 0201-20007SSP 0201-21007SS 0201-21007LL 0201-21007SL 0201-21007SC 0201-21007LC	Class I devices placed on the market in sterile condition	Connecting Tubes Types: 1.8m, 2m, 2.1m, 3m, 3.5m, 3.8m, 4m	Certificate #: DD 60128686 0001 NB#: 0197

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
0201-21007ST 0201-21007SSVS 0201-21007SSP 0201-30007SS 0201-30007LL 0201-30007SL 0201-30007SC 0201-30007LC 0201-30007ST 0201-30007SSVS 0201-30007SSP 0201-35007SS 0201-35007LL 0201-35007SL 0201-35007SC 0201-35007LC 0201-35007ST 0201-35007SSVS 0201-35007SSP 0201-38007SS 0201-38007LL 0201-38007SL 0201-38007SC 0201-38007LC 0201-38007ST 0201-38007SSVS 0201-38007SSP 0201-18006SS 0201-18006LL 0201-18006SL 0201-18006SC 0201-18006LC 0201-18006ST 0201-18006SSVS 0201-18006SSP 0201-20006SS 0201-20006LL 0201-20006SL 0201-20006SC 0201-20006LC 0201-20006ST 0201-20006SSVS 0201-20006SSP 0201-21006SS 0201-21006LL 0201-21006SL 0201-21006SC 0201-21006LC 0201-21006ST 0201-21006SSVS 0201-21006SSP 0201-30006SS 0201-30006LL 0201-30006SL 0201-30006SC 0201-30006LC 0201-30006ST 0201-30006SSVS 0201-30006SSP 0201-35006SS 0201-35006LL			

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
0201-35006SL 0201-35006SC 0201-35006LC 0201-35006ST 0201-35006SSVS 0201-35006SSP 0201-38006SS 0201-38006LL 0201-38006SL 0201-38006SC 0201-38006LC 0201-38006ST 0201-38006SSVS 0201-38006SSP 0201-18005SS 0201-18005LL 0201-18005SL 0201-18005SC 0201-18005LC 0201-18005ST 0201-18005SSVS 0201-18005SSP 0201-20005SS 0201-20005LL 0201-20005SL 0201-20005SC 0201-20005LC 0201-20005ST 0201-20005SSVS 0201-20005SSP 0201-21005SS 0201-21005LL 0201-21005SL 0201-21005SC 0201-21005LC 0201-21005ST 0201-21005SSVS 0201-21005SSP 0201-30005SS 0201-30005LL 0201-30005SL 0201-30005SC 0201-30005LC 0201-30005ST 0201-30005SSVS 0201-30005SSP 0201-35005SS 0201-35005LL 0201-35005SL 0201-35005SC 0201-35005LC 0201-35005ST 0201-35005SSVS 0201-35005SSP 0201-38005SS 0201-38005LL 0201-38005SL 0201-38005SC 0201-38005LC 0201-38005ST 0201-38005SSVS			

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
0201-38005SSP 0203-YCT 0215-010505C 0215-010606C 0215-010707C 0215-010808C 0215-010707CSC			
Skin staple remover Basic UDI-DI: 697269668011QJ Model: SRG-U	Class I devices placed on the market in sterile condition	N/A	Certificate #: DD 60128686 0001 NB#: 0197
Tubing set for chest drainage unit Basic UDI-DI: 697269668019R2 Model: 0203-X1TU 0203-X1TUS 0203-X1TUNA 0203-X1TUNAS 0203-X1TUE 0203-X2TU 0203-X2TUS 0203-X2TUNA 0203-X2TUNAS	Class I devices placed on the market in sterile condition	Chest Drainage Units and Tubing for Chest Drainage Units Types:1C, 2C	Certificate #: DD 60128686 0001 NB#: 0197
Disposable plastic bottle for Chest drainage unit Basic UDI-DI: 697269668020QK Model: 0203-STP3000 0203-STP0700	Class I devices placed on the market in sterile condition	Chest Drainage Units and Tubing for Chest Drainage Units Types:1C, 2C	Certificate #: DD 60128686 0001 NB#: 0197
Chest drainage unit (Plastic bottle) incl. Tubing set for chest drainage unit & Disposable plastic bottle for Chest drainage unit Basic UDI-DI: 697269668018QY Model: 0203-X1P3000 0203-X1P3000S 0203-X1P0700 0203-X1P0700S 0203-X2P3000 0203-X2P3000S 0203-X2P0700 0203-X2P0700S 0203-C32500	Class I devices placed on the market in sterile condition	Chest Drainage Units and Tubing for Chest Drainage Units Types:1C, 2C,3C	Certificate #: DD 60128686 0001 NB#: 0197

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
Chest drainage unit (Glass bottle) incl. Tubing set for chest drainage unit & Reusable glass bottle for Chest drainage unit Basic UDI-DI: 697269668022QP Model: 0203-X1G 0203-X1GS 0203-X2G 0203-X2GS	Class I devices placed on the market in sterile condition	Chest Drainage Units and Tubing for Chest Drainage Units Types:1C, 2C	Certificate #: DD 60128686 0001 NB#: 0197
Disposable skin stapler Basic UDI-DI: 697269668012QL Model: SSG-15W SSG-25W SSG-35W SSG-55W SSG-15R SSG-25R SSG-35R SSG-55R SSG-15H SSG-25H SSG-35H SSG-55H	Class IIa	Skin Staplers Model:H,R,W	Certificate #: DD 60128686 0001 NB#: 0197
Veress Needle Basic UDI-DI: 697269668013QN Model: 0208-VN12 0208-VN15	Class IIa	N/A	Certificate #: DD 60128686 0001 NB#: 0197
Retrieval Bag Basic UDI-DI: 697269668014QQ Model: 0208-RBM200 0208-RBM400 0208-RBM800 0208-RBM1200 0208-RBM1500	Class IIa	N/A	Certificate #: DD 60128686 0001 NB#: 0197
Ring Protect™ Disposable Wound Protector /Retractor Basic UDI-DI: 697269668016QU Model:	Class IIa	Wound protectors types: adjustable	Certificate #: DD 60128686 0001 NB#: 0197

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
0221-060070150 0221-080090150 0221-120130150 0221-150160150 0221-180190200 0221-220230200 0221-180190250 0221-220230250 0221-270280250 0221-320330250			
Silicone Sling Basic UDI-DI: 697269668017QW Model: 0218-01151040R 0218-01151040B 0218-01151040Y 0218-01151040W 0218-01241240R 0218-01241240B 0218-01241240Y 0218-01241240W 0218-01241275R 0218-01241275B 0218-01241275Y 0218-01241275W 0218-01501540R 0218-01501540B 0218-01501540Y 0218-01501540W	Class IIa	Silicone Slings types: Ø1,5 x 1,0 mm x 40 cm, Ø2,4 x 1,2 mm x 40 cm, Ø2,4 x 1,2 mm x 75 cm, Ø5,0 x 1,5 mm x 40 cm	Certificate #: DD 60128686 0001 NB#: 0197
Suction-irrigation Set, parts including Suction-irrigation cannulas Basic UDI-DI: 697269668023QR Model: 0208-SIC05G 0208-SIC05GB 0208-SIC10G 0208-SIC10GB 0208-XXC05 0208-XXC10 0208-XXC05B 0208-XXC10B	Class IIa	Suction-Irrigating Sets types: 5mm, 10mm	Certificate #: DD 60128686 0001 NB#: 0197
Suction-irrigation Set (Economy version) Basic UDI-DI: 697269668024QT Model: 0208-SIC05E 0208-SIC10E	Class IIa	Suction-Irrigating Sets types: 5mm, 10mm	Certificate #: DD 60128686 0001 NB#: 0197
Endoscopic suction set Basic UDI-DI:	Class IIa	Suction-Irrigating Sets	Certificate #:

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
697269668025QV Model: 0208-SXC30007SS05 0208-SXC30007SS10		types: 5mm,10mm	DD 60128686 0001 NB#: 0197
Suction Set (Rigid, Rigid bulb), parts including Suction cannulas (Rigid, Rigid bulb) Basic UDI-DI: 697269668026QX Model: 0202-XXBCH 0202-XXBCX 0202-XXBSH 0202-XXBSX 0202-XXXCH 0202-XXXCX 0202-XXXSH 0202-XXXSX 0202-20007SSBCH 0202-20007SSBCX 0202-20007SSBSH 0202-20007SSBSX 0202-21007SSBCH 0202-21007SSBCX 0202-21007SSBSH 0202-21007SSBSX 0202-30007SSBCH 0202-30007SSBCX 0202-30007SSBSH 0202-30007SSBSX 0202-35007SSBCH 0202-35007SSBCX 0202-35007SSBSH 0202-35007SSBSX 0202-38007SSBCH 0202-38007SSBCX 0202-38007SSBSH 0202-38007SSBSX 0202-20007SSXCH 0202-20007SSXCX 0202-20007SSXSH 0202-20007SSXSX 0202-21007SSXCH 0202-21007SSXCX 0202-21007SSXSH 0202-21007SSXSX 0202-30007SSXCH 0202-30007SSXCX 0202-30007SSXSH 0202-30007SSXSX 0202-35007SSXCH 0202-35007SSXCX 0202-35007SSXSH 0202-35007SSXSX 0202-38007SSXCH 0202-38007SSXCX	Class IIa	Suction Cannulas Model: Rigid Suction Sets Model: Rigid	Certificate #: DD 60128686 0001 NB#: 0197

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
0202-38007SSXSH 0202-38007SSXSX 0202-20006SSBCH 0202-20006SSBCX 0202-20006SSBSH 0202-20006SSBSX 0202-21006SSBCH 0202-21006SSBCX 0202-21006SSBSH 0202-21006SSBSX 0202-30006SSBCH 0202-30006SSBCX 0202-30006SSBSH 0202-30006SSBSX 0202-35006SSBCH 0202-35006SSBCX 0202-35006SSBSH 0202-35006SSBSX 0202-38006SSBCH 0202-38006SSBCX 0202-38006SSBSH 0202-38006SSBSX 0202-20006SSXCH 0202-20006SSXCX 0202-20006SSXSH 0202-20006SSXSX 0202-21006SSXCH 0202-21006SSXCX 0202-21006SSXSH 0202-21006SSXSX 0202-30006SSXCH 0202-30006SSXCX 0202-30006SSXSH 0202-30006SSXSX 0202-35006SSXCH 0202-35006SSXCX 0202-35006SSXSH 0202-35006SSXSX 0202-38006SSXCH 0202-38006SSXCX 0202-38006SSXSH 0202-38006SSXSX			
Suction Set (Mini, Standard), parts including Suction cannulas (Mini, Standard) Basic UDI-DI: 697269668027QZ Model: 0202-XXXCH10G 0202-XXMCX12G 0202-XXMLCX12G 0202-XXXCH18G 0202-XXXCX18G 0202-XXXSH18G 0202-XXXSX18G 0202-XXXCH20G 0202-XXXCX20G 0202-XXXSH20G	Class IIa	Suction Cannulas Model: standard Suction Sets Model: standard	Certificate #: DD 60128686 0001 NB#: 0197

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
0202-XXSX20G 0202-XXCH22G 0202-XXCX22G 0202-XXSH22G 0202-XXSX22G 0202-XXCH24G 0202-XXCX24G 0202-XXSH24G 0202-XXSX24G 0202-XXCH28G 0202-XXCX28G 0202-XXSH28G 0202-XXSX28G 0202-XXCH30G 0202-XXCX30G 0202-XXSH30G 0202-XXSX30G 0202-XXCH18X 0202-XXCX18X 0202-XXSH18X 0202-XXSX18X 0202-XXCH20X 0202-XXCX20X 0202-XXSH20X 0202-XXSX20X 0202-XXCH22X 0202-XXCX22X 0202-XXSH22X 0202-XXSX22X 0202-XXCH24X 0202-XXCX24X 0202-XXSH24X 0202-XXSX24X 0202-XXCH28X 0202-XXCX28X 0202-XXSH28X 0202-XXSX28X 0202-XXCH30X 0202-XXCX30X 0202-XXSH30X 0202-XXSX30X 0202-30007SSXCH10G 0202-20005SSMCX12G 0202-30005MCX12G 0202-20007SSXCH18G 0202-20007SSXCX18G 0202-20007SSXSH18G 0202-20007SSXSX18G 0202-21007SSXCH18G 0202-21007SSXCX18G 0202-21007SSXSH18G 0202-21007SSXSX18G 0202-30007SSXCH18G 0202-30007SSXCX18G 0202-30007SSXSH18G 0202-30007SSXSX18G 0202-35007SSXCH18G 0202-35007SSXCX18G 0202-35007SSXSH18G 0202-35007SSXSX18G 0202-38007SSXCH18G			

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
0202-38007SSXCX18G 0202-38007SSXSH18G 0202-38007SSXSX18G 0202-20007SSXCH20G 0202-20007SSXCX20G 0202-20007SSXSH20G 0202-20007SSXSX20G 0202-21007SSXCH20G 0202-21007SSXCX20G 0202-21007SSXSH20G 0202-21007SSXSX20G 0202-30007SSXCH20G 0202-30007SSXCX20G 0202-30007SSXSH20G 0202-30007SSXSX20G 0202-35007SSXCH20G 0202-35007SSXCX20G 0202-35007SSXSH20G 0202-35007SSXSX20G 0202-38007SSXCH20G 0202-38007SSXCX20G 0202-38007SSXSH20G 0202-38007SSXSX20G 0202-20007SSXCH22G 0202-20007SSXCX22G 0202-20007SSXSH22G 0202-20007SSXSX22G 0202-21007SSXCH22G 0202-21007SSXCX22G 0202-21007SSXSH22G 0202-21007SSXSX22G 0202-30007SSXCH22G 0202-30007SSXCX22G 0202-30007SSXSH22G 0202-30007SSXSX22G 0202-35007SSXCH22G 0202-35007SSXCX22G 0202-35007SSXSH22G 0202-35007SSXSX22G 0202-38007SSXCH22G 0202-38007SSXCX22G 0202-38007SSXSH22G 0202-38007SSXSX22G 0202-20007SSXCH24G 0202-20007SSXCX24G 0202-20007SSXSH24G 0202-20007SSXSX24G 0202-21007SSXCH24G 0202-21007SSXCX24G 0202-21007SSXSH24G 0202-21007SSXSX24G 0202-30007SSXCH24G 0202-30007SSXCX24G 0202-30007SSXSH24G 0202-30007SSXSX24G 0202-35007SSXCH24G 0202-35007SSXCX24G 0202-35007SSXSH24G 0202-35007SSXSX24G 0202-38007SSXCH24G 0202-38007SSXCX24G			

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
0202-38007SSXSH24G 0202-38007SSXSX24G 0202-20007SSXCH28G 0202-20007SSXCX28G 0202-20007SSXSH28G 0202-20007SSXSX28G 0202-21007SSXCH28G 0202-21007SSXCX28G 0202-21007SSXSH28G 0202-21007SSXSX28G 0202-30007SSXCH28G 0202-30007SSXCX28G 0202-30007SSXSH28G 0202-30007SSXSX28G 0202-35007SSXCH28G 0202-35007SSXCX28G 0202-35007SSXSH28G 0202-35007SSXSX28G 0202-38007SSXCH28G 0202-38007SSXCX28G 0202-38007SSXSH28G 0202-38007SSXSX28G 0202-20007SSXCH30G 0202-20007SSXCX30G 0202-20007SSXSH30G 0202-20007SSXSX30G 0202-21007SSXCH30G 0202-21007SSXCX30G 0202-21007SSXSH30G 0202-21007SSXSX30G 0202-30007SSXCH30G 0202-30007SSXCX30G 0202-30007SSXSH30G 0202-30007SSXSX30G 0202-35007SSXCH30G 0202-35007SSXCX30G 0202-35007SSXSH30G 0202-35007SSXSX30G 0202-38007SSXCH30G 0202-38007SSXCX30G 0202-38007SSXSH30G 0202-38007SSXSX30G 0202-20007SSXCH18X 0202-20007SSXCX18X 0202-20007SSXSH18X 0202-20007SSXSX18X 0202-21007SSXCH18X 0202-21007SSXCX18X 0202-21007SSXSH18X 0202-21007SSXSX18X 0202-30007SSXCH18X 0202-30007SSXCX18X 0202-30007SSXSH18X 0202-30007SSXSX18X 0202-35007SSXCH18X 0202-35007SSXCX18X 0202-35007SSXSH18X 0202-35007SSXSX18X 0202-38007SSXCH18X 0202-38007SSXCX18X 0202-38007SSXSH18X			

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
0202-38007SSXSX18X 0202-20007SSXCH20X 0202-20007SSXCX20X 0202-20007SSXSH20X 0202-20007SSXSX20X 0202-21007SSXCH20X 0202-21007SSXCX20X 0202-21007SSXSH20X 0202-21007SSXSX20X 0202-30007SSXCH20X 0202-30007SSXCX20X 0202-30007SSXSH20X 0202-30007SSXSX20X 0202-35007SSXCH20X 0202-35007SSXCX20X 0202-35007SSXSH20X 0202-35007SSXSX20X 0202-38007SSXCH20X 0202-38007SSXCX20X 0202-38007SSXSH20X 0202-38007SSXSX20X 0202-20007SSXCH22X 0202-20007SSXCX22X 0202-20007SSXSH22X 0202-20007SSXSX22X 0202-21007SSXCH22X 0202-21007SSXCX22X 0202-21007SSXSH22X 0202-21007SSXSX22X 0202-30007SSXCH22X 0202-30007SSXCX22X 0202-30007SSXSH22X 0202-30007SSXSX22X 0202-35007SSXCH22X 0202-35007SSXCX22X 0202-35007SSXSH22X 0202-35007SSXSX22X 0202-38007SSXCH22X 0202-38007SSXCX22X 0202-38007SSXSH22X 0202-38007SSXSX22X 0202-20007SSXCH24X 0202-20007SSXCX24X 0202-20007SSXSH24X 0202-20007SSXSX24X 0202-21007SSXCH24X 0202-21007SSXCX24X 0202-21007SSXSH24X 0202-21007SSXSX24X 0202-30007SSXCH24X 0202-30007SSXCX24X 0202-30007SSXSH24X 0202-30007SSXSX24X 0202-35007SSXCH24X 0202-35007SSXCX24X 0202-35007SSXSH24X 0202-35007SSXSX24X 0202-38007SSXCH24X 0202-38007SSXCX24X 0202-38007SSXSH24X 0202-38007SSXSX24X			

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
0202-20007SSXCH28X 0202-20007SSXCX28X 0202-20007SSXSH28X 0202-20007SSXSX28X 0202-21007SSXCH28X 0202-21007SSXCX28X 0202-21007SSXSH28X 0202-21007SSXSX28X 0202-30007SSXCH28X 0202-30007SSXCX28X 0202-30007SSXSH28X 0202-30007SSXSX28X 0202-35007SSXCH28X 0202-35007SSXCX28X 0202-35007SSXSH28X 0202-35007SSXSX28X 0202-38007SSXCH28X 0202-38007SSXCX28X 0202-38007SSXSH28X 0202-38007SSXSX28X 0202-20007SSXCH30X 0202-20007SSXCX30X 0202-20007SSXSH30X 0202-20007SSXSX30X 0202-21007SSXCH30X 0202-21007SSXCX30X 0202-21007SSXSH30X 0202-21007SSXSX30X 0202-30007SSXCH30X 0202-30007SSXCX30X 0202-30007SSXSH30X 0202-30007SSXSX30X 0202-35007SSXCH30X 0202-35007SSXCX30X 0202-35007SSXSH30X 0202-35007SSXSX30X 0202-38007SSXCH30X 0202-38007SSXCX30X 0202-38007SSXSH30X 0202-38007SSXSX30X 0202-20006SSXCH18G 0202-20006SSXCX18G 0202-20006SSXSH18G 0202-20006SSXSX18G 0202-21006SSXCH18G 0202-21006SSXCX18G 0202-21006SSXSH18G 0202-21006SSXSX18G 0202-30006SSXCH18G 0202-30006SSXCX18G 0202-30006SSXSH18G 0202-30006SSXSX18G 0202-35006SSXCH18G 0202-35006SSXCX18G 0202-35006SSXSH18G 0202-35006SSXSX18G 0202-38006SSXCH18G 0202-38006SSXCX18G 0202-38006SSXSH18G 0202-38006SSXSX18G 0202-20006SSXCH20G			

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
0202-20006SSXCX20G 0202-20006SSXSH20G 0202-20006SSXSX20G 0202-21006SSXCH20G 0202-21006SSXCX20G 0202-21006SSXSH20G 0202-21006SSXSX20G 0202-30006SSXCH20G 0202-30006SSXCX20G 0202-30006SSXSH20G 0202-30006SSXSX20G 0202-35006SSXCH20G 0202-35006SSXCX20G 0202-35006SSXSH20G 0202-35006SSXSX20G 0202-38006SSXCH20G 0202-38006SSXCX20G 0202-38006SSXSH20G 0202-38006SSXSX20G 0202-20006SSXCH22G 0202-20006SSXCX22G 0202-20006SSXSH22G 0202-20006SSXSX22G 0202-21006SSXCH22G 0202-21006SSXCX22G 0202-21006SSXSH22G 0202-21006SSXSX22G 0202-30006SSXCH22G 0202-30006SSXCX22G 0202-30006SSXSH22G 0202-30006SSXSX22G 0202-35006SSXCH22G 0202-35006SSXCX22G 0202-35006SSXSH22G 0202-35006SSXSX22G 0202-38006SSXCH22G 0202-38006SSXCX22G 0202-38006SSXSH22G 0202-38006SSXSX22G 0202-20006SSXCH24G 0202-20006SSXCX24G 0202-20006SSXSH24G 0202-20006SSXSX24G 0202-21006SSXCH24G 0202-21006SSXCX24G 0202-21006SSXSH24G 0202-21006SSXSX24G 0202-30006SSXCH24G 0202-30006SSXCX24G 0202-30006SSXSH24G 0202-30006SSXSX24G 0202-35006SSXCH24G 0202-35006SSXCX24G 0202-35006SSXSH24G 0202-35006SSXSX24G 0202-38006SSXCH24G 0202-38006SSXCX24G 0202-38006SSXSH24G 0202-38006SSXSX24G 0202-20006SSXCH28G 0202-20006SSXCX28G			

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
0202-20006SSXSH28G 0202-20006SSXSX28G 0202-21006SSXCH28G 0202-21006SSXCX28G 0202-21006SSXSH28G 0202-21006SSXSX28G 0202-30006SSXCH28G 0202-30006SSXCX28G 0202-30006SSXSH28G 0202-30006SSXSX28G 0202-35006SSXCH28G 0202-35006SSXCX28G 0202-35006SSXSH28G 0202-35006SSXSX28G 0202-38006SSXCH28G 0202-38006SSXCX28G 0202-38006SSXSH28G 0202-38006SSXSX28G 0202-20006SSXCH30G 0202-20006SSXCX30G 0202-20006SSXSH30G 0202-20006SSXSX30G 0202-21006SSXCH30G 0202-21006SSXCX30G 0202-21006SSXSH30G 0202-21006SSXSX30G 0202-30006SSXCH30G 0202-30006SSXCX30G 0202-30006SSXSH30G 0202-30006SSXSX30G 0202-35006SSXCH30G 0202-35006SSXCX30G 0202-35006SSXSH30G 0202-35006SSXSX30G 0202-38006SSXCH30G 0202-38006SSXCX30G 0202-38006SSXSH30G 0202-38006SSXSX30G 0202-20006SSXCH18X 0202-20006SSXCX18X 0202-20006SSXSH18X 0202-20006SSXSX18X 0202-21006SSXCH18X 0202-21006SSXCX18X 0202-21006SSXSH18X 0202-21006SSXSX18X 0202-30006SSXCH18X 0202-30006SSXCX18X 0202-30006SSXSH18X 0202-30006SSXSX18X 0202-35006SSXCH18X 0202-35006SSXCX18X 0202-35006SSXSH18X 0202-35006SSXSX18X 0202-38006SSXCH18X 0202-38006SSXCX18X 0202-38006SSXSH18X 0202-38006SSXSX18X 0202-20006SSXCH20X 0202-20006SSXCX20X 0202-20006SSXSH20X			

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
0202-20006SSXSX20X 0202-21006SSXCH20X 0202-21006SSXCX20X 0202-21006SSXSH20X 0202-21006SSXSX20X 0202-30006SSXCH20X 0202-30006SSXCX20X 0202-30006SSXSH20X 0202-30006SSXSX20X 0202-35006SSXCH20X 0202-35006SSXCX20X 0202-35006SSXSH20X 0202-35006SSXSX20X 0202-38006SSXCH20X 0202-38006SSXCX20X 0202-38006SSXSH20X 0202-38006SSXSX20X 0202-20006SSXCH22X 0202-20006SSXCX22X 0202-20006SSXSH22X 0202-20006SSXSX22X 0202-21006SSXCH22X 0202-21006SSXCX22X 0202-21006SSXSH22X 0202-21006SSXSX22X 0202-30006SSXCH22X 0202-30006SSXCX22X 0202-30006SSXSH22X 0202-30006SSXSX22X 0202-35006SSXCH22X 0202-35006SSXCX22X 0202-35006SSXSH22X 0202-35006SSXSX22X 0202-38006SSXCH22X 0202-38006SSXCX22X 0202-38006SSXSH22X 0202-38006SSXSX22X 0202-20006SSXCH24X 0202-20006SSXCX24X 0202-20006SSXSH24X 0202-20006SSXSX24X 0202-21006SSXCH24X 0202-21006SSXCX24X 0202-21006SSXSH24X 0202-21006SSXSX24X 0202-30006SSXCH24X 0202-30006SSXCX24X 0202-30006SSXSH24X 0202-30006SSXSX24X 0202-35006SSXCH24X 0202-35006SSXCX24X 0202-35006SSXSH24X 0202-35006SSXSX24X 0202-38006SSXCH24X 0202-38006SSXCX24X 0202-38006SSXSH24X 0202-38006SSXSX24X 0202-20006SSXCH28X 0202-20006SSXCX28X 0202-20006SSXSH28X 0202-20006SSXSX28X			

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
0202-21006SSXCH28X 0202-21006SSXCX28X 0202-21006SSXSH28X 0202-21006SSXSX28X 0202-30006SSXCH28X 0202-30006SSXCX28X 0202-30006SSXSH28X 0202-30006SSXSX28X 0202-35006SSXCH28X 0202-35006SSXCX28X 0202-35006SSXSH28X 0202-35006SSXSX28X 0202-38006SSXCH28X 0202-38006SSXCX28X 0202-38006SSXSH28X 0202-38006SSXSX28X 0202-20006SSXCH30X 0202-20006SSXCX30X 0202-20006SSXSH30X 0202-20006SSXSX30X 0202-21006SSXCH30X 0202-21006SSXCX30X 0202-21006SSXSH30X 0202-21006SSXSX30X 0202-30006SSXCH30X 0202-30006SSXCX30X 0202-30006SSXSH30X 0202-30006SSXSX30X 0202-35006SSXCH30X 0202-35006SSXCX30X 0202-35006SSXSH30X 0202-35006SSXSX30X 0202-38006SSXCH30X 0202-38006SSXCX30X 0202-38006SSXSH30X 0202-38006SSXSX30X			
Orthopaedic Suction Set, part including Orthopaedic Suction cannula Basic UDI-DI: 697269668028R3 Model: 0202-30007SSXCKFT 0202-XXXCKFT	Class IIa	Suction Cannulas Model: Orthopaedic Suction Sets Model: Orthopaedic	Certificate #: DD 60128686 0001 NB#: 0197
Thoracentesis/Paracentesis Set Basic UDI-DI: 697269668029R5 Model: 0204-01SN 0204-01VN 0204-02SN 0204-02VN 0204-02PC	Class IIa	T/P Sets model: 0204-01SN, 0204-01VN, 0204- 02SN, 0204-02VN, 0204-02PC	Certificate #: DD 60128686 0001 NB#: 0197
Titanium Ligating Clips	Class IIb excluding Class	Titanium Ligating Clips	Certificate #:

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
Basic UDI-DI: 697269668030QN Model: 0301-01S 0301-01M 0301-01ML 0301-01ML04 0301-01L 0301-06SX 0301-06S 0301-06S10 0301-06SM 0301-06M 0301-06M10 0301-06ML 0301-06ML04 0301-06ML10 0301-06L	IIb implantable non-WET	types: TCJJ,TCTX	HD 60128685 0001 NB#: 0197
Polymer Ligating Clips Basic UDI-DI: 697269668033QU Model: 0301-03M 0301-03ML 0301-03L 0301-03XL 0301-03M04 0301-03ML04 0301-03L04 0301-03XL04 0301-03ML02 0301-03L02 0301-03XL02 0301-10ML 0301-10L 0301-10XL 0301-10ML04 0301-10L04 0301-10XL04 0301-10ML02 0301-10L02 0301-10XL02 0301-10XXL02 0301-10XXL03 0301-10XXL04	Class IIb excluding Class IIb implantable non-WET	Polymer Ligating Clips Types: PCTX-220, PCTX-220-04,PCTX-230, PCTX-230-02, PCTX-230-04, PCTX-240, PCTX-240-02, PCTX-240-04, PCTX-250, PCTX-250-02, PCTX-250-04, ,PCTP-230, PCTP-230-02, PCTP-230-04, PCTP-240, PCTP-240-02, PCTP-240-04, PCTP-250, PCTP-250-02, PCTP-250-04, PCTP-260-02, PCTP-260-03, PCTP-260-04	Certificate #: HD 60128685 0001 NB#: 0197
Disposable Cartridge for Automatic Clip Applier Basic UDI-DI: 697269668031QQ Model: 0301-0907MLC10 0301-0907MLC19	Class IIb excluding Class IIb implantable non-WET	Disposable Cartridges for Automatic Clip Appliers TCAM-30010,TCAM-30019	Certificate #: HD 60128685 0001 NB#: 0197
Product Name: Disposable Endoscopic Surgical Scissor	Class IIb excluding Class	Disposable & Reusable Mono-	Certificate #:

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
Trade Name: Disposable Endoscopic Surgical Instrument Basic UDI-DI: 697269668034QW Model: 0208-DS01XX 0208-DS02XX 0208-DS03XX	IIb implantable non-WET	polar Endoscopic Surgical Instruments types:disposable (Disposable Mono-polar Endoscopic Surgical Instruments)	HD 60128685 0001 NB#: 0197
Product Name: Disposable Endoscopic Surgical Dissector Trade Name: Disposable Endoscopic Surgical Instrument Basic UDI-DI: 697269668035QY Model: 0208-DD01XX 0208-DD01RX	Class IIb excluding Class IIb implantable non-WET	Disposable & Reusable Mono-polar Endoscopic Surgical Instruments types:disposable (Disposable Mono-polar Endoscopic Surgical Instruments)	Certificate #: HD 60128685 0001 NB#: 0197
Product Name: Disposable Endoscopic Surgical Grasper Trade Name: Disposable Endoscopic Surgical Instrument Basic UDI-DI: 697269668036R2 Model: 0208-DG01RX 0208-DG02RX 0208-DG03RX 0208-DG04RX 0208-DG05RX 0208-DG02RXB 0208-DG04RXB 0208-DG05RXB	Class IIb excluding Class IIb implantable non-WET	Disposable & Reusable Mono-polar Endoscopic Surgical Instruments types:disposable (Disposable Mono-polar Endoscopic Surgical Instruments)	Certificate #: HD 60128685 0001 NB#: 0197
Product Name: Reusable Endoscopic Surgical Scissor Trade Name: Reusable limited use endoscopic surgical instrument Basic UDI-DI: 697269668037R4 Model: 0207-LS01XF 0207-LS02XF 0207-LS03XF 0207-LS01XFB	Class IIb excluding Class IIb implantable non-WET	Disposable & Reusable Mono-polar Endoscopic Surgical Instruments types:reusable (Reusable Limited Use Mono-polar Endoscopic Surgical Instruments)	Certificate #: HD 60128685 0001 NB#: 0197

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
Product Name: Reusable Endoscopic Surgical Dissector Trade Name: Reusable limited use endoscopic surgical instrument Basic UDI-DI: 697269668038R6 Model: 0207-LD01XF 0207-LD01RF 0207-LD01RFB	Class IIb excluding Class IIb implantable non-WET	Disposable & Reusable Mono-polar Endoscopic Surgical Instruments types:reusable (Reusable Limited Use Mono-polar Endoscopic Surgical Instruments)	Certificate #: HD 60128685 0001 NB#: 0197
Product Name: Reusable Endoscopic Surgical Grasper Trade Name: Reusable limited use endoscopic surgical instrument Basic UDI-DI: 697269668039R8 Model: 0207-LG01RF 0207-LG02RF 0207-LG03RF 0207-LG04RF 0207-LG05RF 0207-LG04RFB 0207-LG05RFB	Class IIb excluding Class IIb implantable non-WET	Disposable & Reusable Mono-polar Endoscopic Surgical Instruments types:reusable (Reusable Limited Use Mono-polar Endoscopic Surgical Instruments)	Certificate #: HD 60128685 0001 NB#: 0197
Product Name: Reusable Electrosurgery Instrument Kits-Handle Trade Name: Reusable detachable endoscopic surgical instrument Basic UDI-DI: 697269668040QR Model: 0207-HR 0207-HX	Class IIb excluding Class IIb implantable non-WET	Disposable & Reusable Mono-polar Endoscopic Surgical Instruments types:detachable reusable (Reusable Detachable Mono-polar Endoscopic Surgical Instruments)	Certificate #: HD 60128685 0001 NB#: 0197
Product Name: Reusable Electrosurgery Instrument Kits-Shaft Trade Name: Reusable detachable endoscopic surgical instrument Basic UDI-DI: 697269668041QT Model: 0207-S05UN	Class IIb excluding Class IIb implantable non-WET	Disposable & Reusable Mono-polar Endoscopic Surgical Instruments types:detachable reusable (Reusable Detachable Mono-polar Endoscopic Surgical Instruments)	Certificate #: HD 60128685 0001 NB#: 0197

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
Product Name: Reusable Electrosurgery Instrument Kits- Scissor Jaw (Insert) Trade Name: Reusable detachable endoscopic surgical instrument Basic UDI-DI: 697269668042QV Model: 0207-IS01 0207-IS02 0207-IS03	Class IIb excluding Class IIb implantable non-WET	Disposable & Reusable Mono-polar Endoscopic Surgical Instruments types:detachable reusable (Reusable Detachable Mono-polar Endoscopic Surgical Instruments)	Certificate #: HD 60128685 0001 NB#: 0197
Product Name: Reusable Electrosurgery Instrument Kits- Dissector Jaw (Insert) Trade Name: Reusable detachable endoscopic surgical instrument Basic UDI-DI: 697269668043QX Model: 0207-ID01	Class IIb excluding Class IIb implantable non-WET	Disposable & Reusable Mono-polar Endoscopic Surgical Instruments types:detachable reusable (Reusable Detachable Mono-polar Endoscopic Surgical Instruments)	Certificate #: HD 60128685 0001 NB#: 0197
Product Name: Reusable Electrosurgery Instrument Kits-Grasper Jaw (Insert) Trade Name: Reusable detachable endoscopic surgical instrument Basic UDI-DI: 697269668044QZ Model: 0207-IG01 0207-IG02 0207-IG03 0207-IG04 0207-IG05	Class IIb excluding Class IIb implantable non-WET	Disposable & Reusable Mono-polar Endoscopic Surgical Instruments types:detachable reusable (Reusable Detachable Mono-polar Endoscopic Surgical Instruments)	Certificate #: HD 60128685 0001 NB#: 0197

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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-12-13	244545828	Initial issue