Notified Body Confirmation Letter Reference: C792561

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, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 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:

CLARIANCE SAS
18 rue Robespierre
62217 BEAURAINS
France

SRN Number (if available): FR-MF-000023666

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 of the corresponding devices 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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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 the 20 Mar 2023 for the relevant devices.

Place and date:
Høvik, 17.07.2025

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Menaka Singh
Management Representative

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:

- 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)

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 and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Erisma® LP System Implants - *Monoaxial reduction screw / 0370078063V05RPEPT* - *Monoaxial screw / 0370078063V03MAN3* - *Polyaxial screw; cannulated polyaxial screw / 0370078064V02PANL* - *Polyaxial reduction screw / 0370078064V01RPEPG* - *Double set screw / 0370078063V09DSPA* - *Set screw / 0370078064V08SEQ3 Set screw / 0370078063V08SEPN"* - *Bent rod / 0370078066T02TITQJ Bent rod / 0370078067T02TITR3"* - *Rod; straight rod / 0370078066T05TGPX Rod / 0370078068T05TGQR"* - *Straight rod / 0370078067T06TITRX Straight rod / 0370078066T06TITRE"* - *Right offset thoracic hook; left offset thoracic hook; lumbar supra-laminar hook; thoracic supra-laminar hook;*	Class III	**Implants for spinal surgery – Non-sterilized Erisma® implants range for spinal surgery"** (Name Change) - *Monoaxial Reduction Screw* - *Monoaxial Screw* - *Polyaxial Screw ;* - *Cannulated Polyaxial Screw"* - *Polyaxial Reduction Screw* - *Double set screw* - *Set Screw* - *Bent Rod* - *Rod* - *Straight Rod* - *Right Offset Thoracic Hook; Left Offset Thoracic Hook; Lumbar Supra-Laminar Hook; Thoracic Supra-Laminar Hook; Large Right Offset Lumbar Hook; Large Left Offset Lumbar Hook;*	240656-2017-CE-FRA-NA-PS Rev. 6.0 DNV 2460

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
large right offset lumbar hook; large left offset lumbar hook; large laminar hook; large pedicle hook; large transverse hook; large right transverse hook; large left transverse hook; medium laminar hook; medium pedicle hook; small right offset lumbar hook; small left offset lumbar hook; small laminar hook; small pedicle hook; small transverse hook / 0370078065C01HKG7" - *Crosslink bar (transverse bar) / 0370078063V5C6T7LT8D9CLQM* - *Crosslink l; crosslink m ; crosslink s; crosslink xl; crosslink xxl / 0370078067LT09CRS* - *Offset connector / 0370078069C01DECF3* - *Open offset connector / 0370078069C02OPENPJ* - *Dual connector (dual connector large) / 0370078068D01DOMGH* - *Open domino / 0370078068D02VN5*		- *Large Laminar Hook;* - *Large Pedicle Hook;* - *Large Transverse Hook;* - *Large Right Transverse Hook;* - *Large Left Transverse Hook;* - *Medium Laminar Hook;* - *Medium Pedicle Hook;* - *Small Right Offset Lumbar Hook;* - *Small Left Offset Lumbar Hook;* - *Small Laminar Hook;* - *Small Pedicle Hook;* - *small transverse hook* - *Crosslink BAR"* - *Crosslink S* - *Crosslink M* - *Crosslink L* - *Crosslink XL* - *Crosslink XXL"* - *Offset Connector* - *Open Offset Connector* - *Dual Connector* - *Open Domino*	
Erisma IIa - *Secured guide / 0370078069945BRSFK* - *Rod sizing caliper (rod Caliper) / 03700780624CALLA* - *Crosslink template / 03700780699TEXM"*	Class IIa	**Instruments for spinal surgery- Single use Erisma® instruments range for spinal surgery** (Name change) - *Secured Guidewire* **Instruments for spinal surgery–Non-sterilized trials** (Name change) - *Rod sizing caliper (part of Erisma LP instrumentation)* - *Crosslink template (part of Erisma LP instrumentation)*	240656-2017-CE-FRA-NA-PS Rev. 6.0 DNV 2460

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Idys® ALIF Non Sterile - *Vertebral screw / 03700780603IANSHN* - *ALIF cage / 03700780601IANSGY* - *ALIF plate / 03700780602IANVHH*	Class III	**Idys® ALIF** (Name change) - *Vertebral Screw* - *ALIF Cage* - *ALIF Plate*	240656-2017-CE-FRA-NA-PS Rev. 6.0 DNV 2460
Idys® C Cage - *Cervical cage / 03700780601ICPEGL*	Class III	**Implants for spinal surgery-sterile and non-sterile Idys™-C device** (Name change) - *Cervical cage*	240656-2017-CE-FRA-NA-PS Rev. 6.0 DNV 2460
Idys® LIF Cage - *PLIF Cage / 03700780601LIPFJ9* - *TLIF Cage / 03700780601LITFJM*	Class III	**Implants for spinal surgery – Non-sterilized Idys™ implants range for spinal surgery Implants for spinal surgery – sterilized Idys™ LIF range** (Name change) - *PLIF Cage* - *TLIF Cage*	240656-2017-CE-FRA-NA-PS Rev. 6.0 DNV 2460
Erisma® MIS System Implants - *MIS cannulated polyaxial screw / 0370078063V10MSNX* - *MIS straight rod / 0370078066T08TMQS* - *MIS pre-lordosed rod / 0370078066T04TITQY*	Class IIb	**Erisma® Implants range for spinal surgery** (Name change) - *MIS Cannulated Polyaxial Screw* - *MIS Straight Rod* - *MIS Pre-Lordosed Rod*	240656-2017-CE-FRA-NA-PS Rev. 6.0 DNV 2460
Idys® Cages Trials - *Idys®-ALIF trial; Idys®-PLIF trial; Idys®-TLIF fixed trial; Idys®-TLIF trial; Idys®-C trial; Idys®-C fixed trial / 03700780604IATRJH*	Class IIa	**Instruments for spinal surgery– Non-sterilized trials** (Name change) - *ALIF Trial (instrument part of Idys ALIF instrumentation)* - *PLIF Trial* - *TLIF Fixed Trial* - *TLIF Trial* - *Trial* - *Fixed Trial*	240656-2017-CE-FRA-NA-PS Rev. 6.0 DNV 2460

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: NA

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Spinal Instrumentation - *SPREADER / 0370078069906BOF7* - *SHAVER / 0370078069947DLG8* - *ROUNDED SHAVER / 0370078069947DLG8* - *ROUNDED SHAVER / 0370078069947DLG8* - *ROUNDED SHAVER / 0370078069947DLG8* - *ROUNDED SHAVER / 0370078069947DLG8* - *ROUNDED SHAVER / 0370078069947DLG8* - *ROUNDED SHAVER / 0370078069947DLG8* - *ROUNDED SHAVER / 0370078069947DLG8* - *ROUNDED SHAVER / 0370078069947DLG8* - *ROUNDED SHAVER / 0370078069947DLG8* - *ROUNDED SHAVER / 0370078069947DLG8* - *ROUNDED SHAVER / 0370078069947DLG8* - *ROUNDED SHAVER / 0370078069947DLG8* - *CURETTE / 0370078069948CUGU* - *CURETTE / 0370078069948CUGU* - *CURVED CURETTE / 0370078069948CUGU* - *STRAIGHT CURETTE / 0370078069948CUGU* - *RIGHT CUP CURETTE / 0370078069948CUGU* - *LEFT CUP CURETTE / 0370078069948CUGU* *STRAIGHT DISC RONGEUR / 0370078069953PDSGC* - *DISC RONGEUR / 45°0370078069953PDSGC* - *CURVED DISC RONGEUR / 0370078069953PDSGC* - *PLIF CAGE INSERTER / 0370078069956PCGU* - *PLIF CAGE HOLDER / 0370078069956PCGU* - *PLIF CAGE HOLDER /*	Class Ir	N/A	NA

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
0370078069956PCGU - *TLIF CAGE HOLDER / 0370078069956PCGU* - *TLIF CAGE HOLDER / 0370078069956PCGU* - *TLIF CAGE INSERTER / 0370078069956PCGU* - *TLIF CAGE INSERTER / 0370078069956PCGU* - *TLIF CAGE INSERTER / 0370078069956PCGU* - *TLIF CAGE INSERTER 25° / 0370078069956PCGU* - *INCLINED TLIF CAGE HOLDER / 0370078069956PCGU* - *STRAIGHT TLIF CAGE HOLDER / 0370078069956PCGU* - *TLIF TRIAL INSERTER / 0370078069956PCGU* - *PLIF CAGE PUSHER / 0370078069963PCGFU* - *CURVED TLIF CAGE PUSHER / 0370078069963PCGFU* - *STRAIGHT TLIF CAGE PUSHER / 0370078069963PCGFU* - *STRAIGHT TLIF CAGE PUSHER / 0370078069963PCGFU* - *LATERAL TLIF CAGE PUSHER / 0370078069963PCGFU* - *INTER-LAMINAR DISTRACTOR / 0370078069967DISG6* - *SCREW-TO-SCREW DISTRACTOR / 0370078069967DISG6* - *NERVE ROOT RETRACTOR / 0370078069974EDRFG* - *NERVE ROOT RETRACTOR / 0370078069974EDRFG* - *RASP / 0370078069978RAPHY* - *OSTEOTOME / 0370078069980OSHG* - *CURVED OSTEOTOME / 0370078069980OSHG* - *CAGE HOLDER / 0370078069956PCGU* - *CAGE HOLDER / 0370078069956PCGU* - *RASP / 0370078069978RAPHY* - *TIGHTENING WRENCH / 0370078069901CS02CHTB* - *SELF-RETAINING SET SCREW DRIVER / 0370078069934TVHN*			

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
- *SELF RETAINING SET SCREW DRIVER / 0370078069934TVHN* - *TIGHTENING WRENCH / 0370078069901CS02CHTB* - *TIGHTENING KEY / 0370078069901CS02CHTB* - *TIGHTENING WRENCH / 0370078069901CS02CHTB* - *SNAP FIT TIGHTENING WRENCH / 0370078069901CS02CHTB* - *T20 TIGHTENING WRENCH / 0370078069901CS02CHTB* - *SNAP FIT T20 TIGHTENING WRENCH FOR CROSSLINK / 0370078069901CS02CHTB* - *T30 TIGHTENING WRENCH / 0370078069901CS02CHTB* - *TIGHTENING WRENCH T30 / 0370078069901CS02CHTB* - *T30 TIGHTENING WRENCH / 0370078069901CS02CHTB* - *HEXAGONAL WRENCH / 0370078069901CS02CHTB* - *HEXAGONAL WRENCH / 0370078069901CS02CHTB* - *HEXAGONAL WRENCH / 0370078069901CS02CHTB* - *HEXAGONAL WRENCH / 0370078069901CS02CHTB* - *SNAP FIT HEXAGONAL WRENCH / 0370078069901CS02CHTB* - *SNAP FIT HEXAGONAL WRENCH / 0370078069901CS02CHTB* - *T20 WRENCH / 0370078069901CS02CHTB* - *COUNTER TORQUE / 0370078069903CCE3* - *COUNTER TORQUE / 0370078069903CCE3* - *COUNTER TORQUE / 0370078069903CCE3* - *COUNTER TORQUE / 0370078069903CCE3* - *COUNTER TORQUE / 0370078069903CCE3* - *COUNTER TORQUE / 0370078069903CCE3* - *COUNTER TORQUE / 0370078069903CCE3* - *COUNTER TORQUE / 0370078069903CCE3* - *COUNTER TORQUE / 0370078069903CCE3* - *COUNTER TORQUE FOR REDUCTION SCREWS /*			

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
0370078069903CCE3 - *GUIDEWIRE / 0370078069904BRF3* - *GUIDEWIRE / 0370078069904BRF3* - *GUIDEWIRE / 0370078069904BRF3* - *GUIDEWIRE / 0370078069904BRF3* - *GUIDEWIRE / 0370078069904BRF3* - *GUIDEWIRE / 0370078069904BRF3* - *GUIDEWIRE / 0370078069904BRF3* - *GUIDEWIRE / 0370078069904BRF3* - *GUIDE WIRE SHARP 500 MM / 0370078069904BRF3* - *RING FOR MIS SCREW / 0370078069905BAE6* - *RING FOR MIS SCREW / 0370078069905BAE6* - *RING FOR MIS SCREW / 0370078069905BAE6* - *BODY OF PERSUADER / 0370078069907CPFH* - *DILATOR / 0370078069908DCEX* - *DILATOR / 0370078069908DCEX* - *DILATOR / 0370078069908DCEX* - *DILATOR / 0370078069908DCEX* - *DILATOR / 0370078069908DCEX* - *SLEEVE / 0370078069909DOFU* - *REDUCTION SLEEVE / 0370078069909DOFU* - *REDUCTION DRIVER / 0370078069909DOFU* - *SLEEVE FOR SCREWDRIVER / 0370078069909DOFU* - *SLEEVE FOR MONOAXIAL SCREWDRIVER / 0370078069909DOFU* - *SHORT SLEEVE FOR SCREWDRIVER / 0370078069909DOFU* - *TISSUE RETRACTOR / 0370078069910ECDZ* - *DOUBLE SET SCREW REMOVER /*			

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
0370078069912EBE9 - *FRONTAL RIGHT BENDER / 0370078069913FCEK* - *RIGHT BENDER / 0370078069913FCEK* - *FRONTAL LEFT BENDER / 0370078069913FCEK* - *LEFT BENDER / 0370078069913FCEK* - *RIGHT HORIZONTAL BENDER / 0370078069913FCEK* - *RIGHT HORIZONTAL BENDER / 0370078069913FCEK* - *LEFT HORIZONTAL BENDER / 0370078069913FCEK* - *LEFT HORIZONTAL BENDER / 0370078069913FCEK* - *GUIDE FOR RESCUE TUBE / 0370078069914GTRF8* - *HOOK IMPACTOR / 0370078069915ICF6* - *PERSUADER / 0370078069916ITGD* - *PERSUADER / 0370078069916ITGD* - *PERSUADER / 0370078069916ITGD* - *PERSUADER / 0370078069916ITGD* - *PERSUADER / 0370078069916ITGD* - *LUMBAR ROD REDUCER / 0370078069916ITGD* - *KOBE PERSUADER / 0370078069916ITGD* - *PERSUADER / 0370078069916ITGD* - *PERSUADER / 0370078069916ITGD* - *PERSUADER / 0370078069916ITGD* - *ROD GAUGE / 0370078069917JVGR* - *ROD GAUGE / 0370078069917JVGR* - *DEROTATION LEVER / 0370078069920LDEX* - *TAB REMOVER / 0370078069921LRFY* - *BREAKING LEVER / 0370078069921LRFY* - *ROCKER / 0370078069922LIFK* - *PEDICLE SOUNDER /*			

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
0370078069925PPGU - *PERSUADER / 0370078069916ITGD* - *PERSUADER FOR STANDARD SCREW / 0370078069926PVHD* - *PERSUADER FOR REDUCTION SCREW / 0370078069926PVHD* - *BONE AWL / 0370078069927PCGC* - *BONE AWL / 0370078069927PCGC* - *BONE AWL / 0370078069927PCGC* - *ROD REDUCER / 0370078069928RIH3* - *THORACIC ROD REDUCER / 0370078069928RIH3* - *ROCKER / 0370078069929ROHL* - *ROCKER / 0370078069929ROHL* - *COBB ELEVATOR WITH STOP / 0370078069930RUGS* - *LAMINAR ELEVATOR / 0370078069930RUGS* - *PEDICLE ELEVATOR / 0370078069930RUGS* - *TRANSVERSE ELEVATOR / 0370078069930RUGS* - *LUMBAR PROBE / 0370078069931SOGN* - *STRAIGHT LUMBAR PROBE / 0370078069931SOGN* - *CURVED THORACIC PROBE / 0370078069931SOGN* - *TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *TAP /			

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
0370078069932TAG2 - *TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *ROD OF SCREWDRIVER / 0370078069933TTHD* - *ROD OF SCREWDRIVER / 0370078069933TTHD* - *ROD OF SCREWDRIVER / 0370078069933TTHD* - *SCREWDRIVER SHAFT / 0370078069933TTHD* - *SCREWDRIVER SHAFT / 0370078069933TTHD* - *SCREWDRIVER SHAFT / 0370078069933TTHD* - *ROD OF SCREWDRIVER / 0370078069933TTHD* - *SCREWDRIVER SHAFT / 0370078069933TTHD* - *SCREWDRIVER SHAFT / 0370078069933TTHD* - *MONOAXIAL SCREWDRIVER ROD / 0370078069933TTHD* - *MONOAXIAL SCREWDRIVER SHAFT / 0370078069933TTHD* - *MONOAXIAL REDUCTION SCREWDRIVER ROD / 0370078069933TTHD* - *POLYAXIAL SCREWDRIVER ROD / 0370078069933TTHD* - *POLYAXIAL REDUCTION SCREWDRIVER ROD / 0370078069933TTHD* - *CANNULATED POLY SCREW DRIVER / 0370078069933TTHD* - *SCREWDRIVER / 0370078069934TVHN* - *SCREWDRIVER / 0370078069934TVHN* - *SCREWDRIVER / 0370078069934TVHN* - *SCREWDRIVER / 0370078069934TVHN* - *SCREWDRIVER / 0370078069934TVHN* - *SCREWDRIVER / 0370078069934TVHN* - *SCREWDRIVER / 0370078069934TVHN* - *SCREWDRIVER /*			

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
0370078069934TVHN - *SCREWDRIVER / 0370078069934TVHN* - *SCREWDRIVER / 0370078069934TVHN* - *SCREWDRIVER / 0370078069934TVHN* - *SCREWDRIVER / 0370078069934TVHN* - *SCREWDRIVER / 0370078069934TVHN* - *SCREWDRIVER / 0370078069934TVHN* - *SCREWDRIVER / 0370078069934TVHN* - *SCREWDRIVER / 0370078069934TVHN* - *SCREWDRIVER / 0370078069934TVHN* - *SCREWDRIVER / 0370078069934TVHN* - *SCREWDRIVER / 0370078069934TVHN* - *SCREWDRIVER / 0370078069934TVHN* - *SCREWDRIVER / 0370078069934TVHN* - *CANNULATED SCREWDRIVER / 0370078069934TVHN* - *CANNULATED SCREWDRIVER / 0370078069934TVHN* - *CANNULATED SCREWDRIVER / 0370078069934TVHN* - *REVISION SCREWDRIVER / 0370078069934TVHN* - *DOUBLE SET SCREW DRIVER / 0370078069934TVHN* - *SCREWDRIVER FOR REDUCTION SCREWS / 0370078069934TVHN* - *SCREWDRIVER FOR MONOAXIAL REDUCTION SCREW / 0370078069934TVHN* - *HOLDING SCREWDRIVER / 0370078069934TVHN* - *HOLDING SCREWDRIVER / 0370078069934TVHN* - *REDUCTION SCREWDRIVER / 0370078069934TVHN* - *PEDICLE TARGETING NEEDLE / 0370078069935TRHK* - *COMPRESSOR / 0370078069941PCFU* - *DISTRACTOR /*			

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
0370078069942PDG3 - *STRAIGHT ROD HOLDING FORCEPS / 0370078069943PTTHK* - *ANGLED ROD HOLDING FORCEPS / 0370078069943PTTHK* - *ROD GRIPPER / 0370078069954PSTJ2* - *GUIDE / 0370078069955VIHM* - *TIGHTENING TIP HOLDER / 0370078069956PCGU* - *ROD INSERTER / 0370078069956PCGU* - *ROD INSERTER / 0370078069956PCGU* - *STRAIGHT ROD HOLDER / 0370078069956PCGU* - *IMPLANT HOLDER / 0370078069956PCGU* - *QUICK CONNECT ROD / 0370078069959TEQJ9* - *QUICK CONNECT ROD / 0370078069959TEQJ9* - *QUICK CONNECT ROD / 0370078069959TEQJ9* - *ROD PUSHER / 0370078069960PTGGS* - *ROD PUSHER / 0370078069960PTGGS* - *ROD PUSHER / 0370078069960PTGGS* - *SET SCREW HOLDER / 0370078069962PVSJ6* - *SET SCREW HOLDER / 0370078069962PVSJ6* - *SET SCREW HOLDER / 0370078069962PVSJ6* - *SET SCREW HOLDER / 0370078069962PVSJ6* - *SET SCREW HOLDER / 0370078069962PVSJ6* - *HOOK PUSHER / 0370078069963PCGFU* - *SCREW HEAD POSITIONER / 0370078069964PTVJL* - *SCREW HEAD POSITIONER / 0370078069964PTVJL* - *SCREW HEAD POSITIONER / 0370078069964PTVJL* - *SCREW POSITIONNER / 0370078069964PTVJL* - *CROSSLINK HOLDER / 0370078069966PPCHG* - *CROSSLINK CONNECTOR*			

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
HOLDING FORCEP / 0370078069966PPCHG - *HOOK HOLDER / 0370078069966PPCHG* - *OFFSET IMPLANT HOLDER FORCEPS / 0370078069966PPCHG* - *LATERAL IMPLANTS HOLDER FORCEPS / 0370078069966PPCHG* - *CROSSLINK HOLDER / 0370078069966PPCHG* - *PROTECTIVE TUBE / 0370078069968TBPJ2* - *PROTECTOR TUBE / 0370078069968TBPJ2* - *PROTECTOR TUBE / 0370078069968TBPJ2* - *PROTECTOR TUBE / 0370078069968TBPJ2* - *GUIDEWIRE INSERTER / 0370078069969TDBHK* - *GUIDEWIRE INSERTER / 0370078069969TDBHK* - *SCREWDRIVER BODY / 0370078069970TTAHD* - *ASSEMBLY OF SCREWDRIVER TUBE / 0370078069970TTAHD* - *ASSEMBLY OF SCREWDRIVER TUBE / 0370078069970TTAHD* - *ASSEMBLY OF SCREWDRIVER TUBE / 0370078069970TTAHD* - *PERSUADER TUBE FOR REDUCTION SCREW / 0370078069971TPSJC* - *PERSUADER TUBE FOR STANDARD SCREW / 0370078069971TPSJC* - *GUIDING TUBE / 0370078069975TGEHH* - *SET SCREW INSERTION GUIDE / 0370078069975TGEHH* - *GUIDING TUBE / 0370078069975TGEHH* - *HOLDER TUBE FOR PERSUADER / 0370078069977TPPKG* - *ANGLED BENDING FORCEPS / 0370078069985PCAGL* - *SCREW HEAD POSITIONER / 0370078069986RTVL2* - *RESCUE TUBE /*			

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
0370078069987TDRJT - *TIGHTENING WRENCH / 0370078069901CS02CHTB* - *SELF-RETAINING WRENCH / 0370078069901CS02CHTB* - *COUNTER TORQUE / 0370078069903CCE3* - *SPREADER / 0370078069906BOF7* - *SPREADER / 0370078069906BOF7* - *SPREADER / 0370078069906BOF7* - *ROUNDED DISTRACTOR / 0370078069906BOF7* - *ROUNDED DISTRACTOR / 0370078069906BOF7* - *COBB'S ELEVATOR / 0370078069930RUGS* - *SHAVER / 0370078069947DLG8* - *SHAVER / 0370078069947DLG8* - *SHAVER / 0370078069947DLG8* - *SHAVER /* - *0370078069947DLG8* - *SHAVER / 0370078069947DLG8* - *SHAVER / 0370078069947DLG8* - *CURETTE / 0370078069948CUGU* - *CURETTE / 0370078069948CUGU* - *HOLLOW CHISEL TEMPLATE / 0370078069949GCG9* - *HOLLOW CHISEL TEMPLATE / 0370078069949GCG9* - *HOLLOW CHISEL TEMPLATE / 0370078069949GCG9* - *HOLLOW CHISEL TEMPLATE / 0370078069949GCG9* - *HOLLOW CHISEL TEMPLATE / 0370078069949GCG9* *STRAIGHT DISC RONGEUR / 0370078069953PDSGC* *STRAIGHT DISC RONGEUR / 0370078069953PDSGC* *STRAIGHT DISC RONGEUR / 0370078069953PDSGC* *INCLINED 30° DISC RONGEUR / 0370078069953PDSGC* *INCLINED 30° DISC RONGEUR /*			

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
0370078069953PDSGC *CAGE INSERTER /* *0370078069956PCGU* *TRIAL INSERTER /* *0370078069956PCGU* *MEDIAL CAGE PUSHER /* *0370078069963PCGFU* *FOOTPRINT GAUGE /* *0370078069972GDEEJ* *FOOTPRINT GAUGE /* *0370078069972GDEEJ* *HOLLOW CHISEL /* *0370078069973GGEF2* *HOLLOW CHISEL /* *0370078069973GGEF2* - *BONE RONGEUR /* *0370078069979RKJF* - *BONE RONGEUR /* *0370078069979RKJF* - *DISTRACTION FORCEPS /* *0370078069981DILF4* - *MEASURING GAUGE /* *0370078069983JGEFU* - *TAP /* *0370078069932TAG2* - *TAP /* *0370078069932TAG2* - *RESCUE SCREWDRIVER T15 /* *0370078069934TVHN* - *LOCKING SYSTEM SCREWDRIVER /* *0370078069934TVHN* - *SCREWDRIVER T15 /* *0370078069934TVHN* - *DRIIL /* *0370078069950MEFR* - *DRILL /* *0370078069950MEFR* - *DRILL /* *0370078069950MEFR* - *DRILL /* *0370078069950MEFR* - *DRILL /* *0370078069950MEFR* - *DRILL /* *0370078069950MEFR* - *PUNCH /* *0370078069952PEGC* - *SHORT PUNCH /* *0370078069952PEGC* - *DOUBLE FIXE DRILL /* *0370078069955VIHM* - *VARIABLE DRILL /* *0370078069955VIHM*			

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
- *CAGE PLATE HOLDER / 0370078069956PCGU* - *CERVICAL PLATE HOLDER / 0370078069956PCGU* - *DISTRACTION PIN / 0370078069957PDDGA* - *DISTRACTION PIN / 0370078069957PDDGA* - *DISTRACTION PIN / 0370078069957PDDGA* - *PLATE HOLDING FORCEPS / 0370078069966PPCHG* - *OFFSET CERVICAL PLATE HOLDER / 0370078069966PPCHG* - *DISTRACTOR / 0370078069967DISG6* - *POSITIONING PIN / 0370078069984PDPHE* - *LOCKING NUT / 0370078069989EDVH6* - *SCREWDRIVER T15 / 0370078069934TVHN* - *ARTICULATED WRENCH / 0370078069901CS02CHTB* - *IDYS-C ZP 3DTI ANGLED SCREWDRIVER / 0370078069934TVHN* - *RESCUE SCREWDRIVER / 0370078069934TVHN* - *FLEXIBLE DRILL / 0370078069950MEFR* - *IDYS-C ZP 3DTI ANGLED DRILL / 0370078069950MEFR* - *DRILL / 0370078069950MEFR* - *STRAIGHT PUNCH / 0370078069952PEGC* - *ANGULATED PUNCH / 0370078069952PEGC* - *SINGLE BARREL DRILL GUIDE / 0370078069955VIHM* - *CAGE HOLDER / 0370078069956PCGU* *TIGHTENING WRENCH / 0370078069901CS02CHTB* - *ROUNDED DISTRACTOR / 0370078069906BOF7* - *ROUNDED DISTRACTOR / 0370078069906BOF7* - *ANGULATED SCREWDRIVER (35°) / 0370078069934TVHN* - *35° ANGULATED SCREWDRIVER / 0370078069934TVHN* - *ANGLED PUNCH /*			

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
0370078069952PEGC - *ZP GUIDE / 0370078069955VIHM* - *CAGE HOLDER / 0370078069956PCGU* *BODY OF CAGE HOLDER / 0370078069958CPGFS* - *ALIF-ZP CAGE-HOLDER BODY / 0370078069958CPGFS* - *ROD OF CAGE HOLDER / 0370078069976TPGJP* - *ALIF-ZP CAGE-HOLDER ROD / 0370078069976TPGJP* - *HOLDING TUBE / 0370078069988TPVLE* - *STRAIGHT PUNCH / 0370078069952PEGC* - *IDYS-ALIF CAGE-HOLDER BODY / 0370078069958CPGFS* - *IDYS-ALIF CAGE-HOLDER ROD / 0370078069976TPGJP* - *IDYS-C 3DTI IMPLANT HOLDER / 0370078069956PCGU* - *T15 TIGHTENING WRENCH / 0370078069901CS02CHTB* - *GUIDE / 0370078069955VIHM* - *GUIDE / 0370078069955VIHM* - *GUIDE / 0370078069955VIHM* - *GUIDE / 0370078069955VIHM* - *GUIDE / 0370078069955VIHM* - *BODY OF IMPLANT REMOVER / 0370078069956PCGU* - *ROD OF IMPLANT REMOVER / 0370078069956PCGU* - *SHIM FOR LATERAL RETRACTOR'S BLADE / 0370078069996LATHJ* - *BLADE'S SHIM INSERTER/REMOVER / 0370078069997LATHR* - *HEXAGONAL WRENCH / 0370078069901CS02CHTB* - *SLEEVE / 0370078069909DOFU* - *SLEEVE / 0370078069909DOFU* - *SLEEVE / 0370078069909DOFU* - *PEDICLE SOUNDER /*			

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
0370078069925PPGU - *PEDICLE SOUNDER / 0370078069925PPGU* - *BONE AWL / 0370078069927PCGC* - *BONE AWL / 0370078069927PCGC* - *BONE AWL / 0370078069927PCGC* - *CANNULATED AWL / 0370078069927PCGC* - *LUMBAR PROBE / 0370078069931SOGN* - *CURVED LUMBAR PROBE / 0370078069931SOGN* - *STRAIGHT LUMBAR PROBE / 0370078069931SOGN* - *STRAIGHT LUMBAR PROBE / 0370078069931SOGN* - *STRAIGHT LUMBAR PROBE / 0370078069931SOGN* - *PEDICLE PROBE / 0370078069931SOGN* - *THORACIC PROBE / 0370078069931SOGN* - *CURVED THORACIC PROBE / 0370078069931SOGN* - *STRAIGHT THORACIC PROBE / 0370078069931SOGN* - *STRAIGHT THORACIC PROBE / 0370078069931SOGN* - *TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *TAP /			

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
0370078069932TAG2 - *TAP / 0370078069932TAG2* - *CANNULATED TAP / 0370078069932TAG2* - *TAP / 0370078069932TAG2* - *CANNULATED TAP / 0370078069932TAG2* - *CANNULATED TAP / 0370078069932TAG2* - *CANNULATED TAP / 0370078069932TAG2* - *CANNULATED TAP / 0370078069932TAG2* - *CANNULATED TAP /*			

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
0370078069932TAG2 - *CANNULATED TAP / 0370078069932TAG2* - *CANNULATED TAP / 0370078069932TAG2* - *CANNULATED TAP / 0370078069932TAG2* - *CANNULATED TAP / 0370078069932TAG2* - *CANNULATED TAP / 0370078069932TAG2* - *CANNULATED TAP / 0370078069932TAG2* - *CANNULATED TAP / 0370078069932TAG2* - *CANNULATED TAP / 0370078069932TAG2* - *REVISION SCREWDRIVER / 0370078069934TVHN* - *PEDICLE TARGETING NEEDLE / 0370078069935TRHK* - *CENTRAL CHISEL / 0370078069936CSG7* - *LATERAL CHISEL / 0370078069936CSG7* - *T20 TIGHTENING TIP / 0370078069939ESGU* - *COMPRESSOR / 0370078069941PCFU* - *ADJUSTABLE COMPRESSOR / 0370078069941PCFU* - *COMPRESSOR / 0370078069941PCFU* - *COMPRESSION FORCEPS / 0370078069941PCFU* - *COMPRESSOR / 0370078069941PCFU* - *DISTRACTOR / 0370078069942PDG3* - *DISTRACTOR / 0370078069942PDG3* - *DISTRACTOR / 0370078069942PDG3* - *DISTRACTOR / 0370078069942PDG3* - *STRAIGHT ROD HOLDING FORCEPS MIS / 0370078069943PTTHK* - *LEFT ANGLED ROD HOLDING FORCEPS MIS / 0370078069943PTTHK* - *RIGHT ANGLED ROD HOLDING FORCEPS MIS / 0370078069943PTTHK*			

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
- *ROD GRIPPER / 0370078069954PSTJ2* - *ROD GRIPPER / 0370078069954PSTJ2* - *ROD GRIPPER / 0370078069954PSTJ2* - *ROD GRIPPER / 0370078069954PSTJ2* - *ROD HOLDER / 0370078069956PCGU* - *ANGLED ROD HOLDING FORCEPS / 0370078069956PCGU* - *STRAIGHT ROD HOLDING FORCEPS / 0370078069956PCGU* - *ROD PUSHER 0370078069960PTGGS* - *ROD PUSHER 0370078069960PTGGS* - *ROD PUSHER 0370078069960PTGGS* - *TARGETING TIP 0370078069996EMPHB* - *STRAIGHT LUMBAR PROBE / 0370078069931SOGN* - *BONE AWL / 0370078069927PCGC*			

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 and 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 device	MDD 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
2025.07.17	C792561	Initial issue

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607.
- Significant changes to design or intended purpose of the devices.
- Changes in the quality system affecting production.
- Periodical audits not held within the timeframe.