ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-027

issued for the company

CHIRANA T. Injecta, a.s.

Nám. Dr. A. Schweitzera 194, 916 01 Stará Turá, Slovakia

List of medical devices covered by the EU Quality Management System Certificate:

Arterio-Venous System Devices

Product	Trade Name	Models	REF code
I.V. Cannula for Single Use	CHIRAFLEX / CHIRAFLEX SAFETY	14G with port, snap fit cap & suturable wings	CHFX0101445
		14G with port, snap fit cap & suturable wings	CHFX0101450
		16G with port, snap fit cap & suturable wings	CHFX0101645
		17G with port, snap fit cap & suturable wings	CHFX0101745
		18G with port, snap fit cap & suturable wings	CHFX0101832
		18G with port, snap fit cap & suturable wings	CHFX0101840
		18G with port, snap fit cap & suturable wings	CHFX0101845
		20G with port, snap fit cap & suturable wings	CHFX0102030
		20G with port, snap fit cap & suturable wings	CHFX0102032
		20G with port, snap fit cap & suturable wings	CHFX0102033
		22G with port, snap fit cap & suturable wings	CHFX0102225
		24G with port, snap fit cap & suturable wings	CHFX0102419
		26G with port, snap fit cap & suturable wings	CHFX0102619
		14G without port & with wings (without injection port)	CHFX0201445
		16G without port & with wings (without injection port)	CHFX0201645
		17G without port & with wings (without injection port)	CHFX0201745
		18G without port & with wings (without injection port)	CHFX0201845
		20G without port & with wings (without injection port)	CHFX0202032
		20G without port & with wings (without injection port)	CHFX0202033
		22G without port & with wings (without injection port)	CHFX0202225
		24G without port & with wings (without injection port)	CHFX0202419
		26G without port & with wings (without injection port)	CHFX0202619
		14G without injection port & without wings	CHFX0301445
		16G without injection port & without wings	CHFX0301645
		17G without injection port & without wings	CHFX0301745

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 30.09.2022
Valid until 30.09.2027

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CHIRANA T. Injecta, a.s.

Nám. Dr. A. Schweitzera 194, 916 01 Stará Turá, Slovakia

List of medical devices covered by the EU Quality Management System Certificate:

Arterio-Venous System Devices

Product	Trade Name	Models	REF code
I.V. Cannula for Single Use	CHIRAFLEX / CHIRAFLEX SAFETY	18G without injection port & without wings	CHFX0301832
		18G without injection port & without wings	CHFX0301845
		20G without injection port & without wings	CHFX0302032
		22G without injection port & without wings	CHFX0302225
		24G without injection port & without wings	CHFX0302419
		26G without injection port & without wings	CHFX0302619
		14G safety - with port, snap fit cap & suturable wings	CHFXS0101445
		16G safety - with port, snap fit cap & suturable wings	CHFXS0101645
		17G safety - with port, snap fit cap & suturable wings	CHFXS0101745
		18G safety - with port, snap fit cap & suturable wings	CHFXS0101832
		18G safety - with port, snap fit cap & suturable wings	CHFXS0101845
		20G safety - with port, snap fit cap & suturable wings	CHFXS0102032
		20G safety - with port, snap fit cap & suturable wings	CHFXS0102033
		22G safety - with port, snap fit cap & suturable wings	CHFXS0102225
		24G safety - with port, snap fit cap & suturable wings	CHFXS0102419
		26G safety - with port, snap fit cap & suturable wings	CHFXS0102619
		14G safety - without port & with wings (without injection port)	CHFXS0201445
		16G safety - without port & with wings (without injection port)	CHFXS0201645
		17G safety - without port & with wings (without injection port)	CHFXS0201745
		18G safety - without port & with wings (without injection port)	CHFXS0201832
		18G safety - without port & with wings (without injection port)	CHFXS0201845
		20G safety - without port & with wings (without injection port)	CHFXS0202032
		22G safety - without port & with wings (without injection port)	CHFXS0202225
		24G safety - without port & with wings (without injection port)	CHFXS0202419
		26G safety - without port & with wings (without injection port)	CHFXS0202619

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 30.09.2022
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ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-027

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CHIRANA T. Injecta, a.s.

Nám. Dr. A. Schweitzera 194, 916 01 Stará Turá, Slovakia

List of medical devices covered by the EU Quality Management System Certificate:

Arterio-Venous System Devices

Product	Trade Name	Models	REF code
I.V. Cannula for Single Use	CHIRAFLEX / CHIRAFLEX SAFETY	14G safety - without injection port & without wings	CHFXS0301445
		16G safety - without injection port & without wings	CHFXS0301645
		17G safety - without injection port & without wings	CHFXS0301745
		18G safety - without injection port & without wings	CHFXS0301832
		18G safety - without injection port & without wings	CHFXS0301845
		20G safety - without injection port & without wings	CHFXS0302032
		22G safety - without injection port & without wings	CHFXS0302225
		24G safety - without injection port & without wings	CHFXS0302419
		26G safety - without injection port & without wings	CHFXS0302619

Versions:
- with port, snap fit cap & suturable wings
- without injection port & with wings
- without injection port & without wings
- safety versions

Sizes: 14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 30.09.2022
Valid until 30.09.2027

ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-027

issued for the company

CHIRANA T. Injecta, a.s.

Nám. Dr. A. Schweitzera 194, 916 01 Stará Turá, Slovakia

Intended purpose of medical devices covered by the EU Quality Management System Certificate:

Infusion Set for Single Use: CHIRAPLUS G / CHIRAPLUS P - administration liquids and drugs into the circulation system by using of intravenous catheters and cannulas

Transfusion Set for Single Use: CHIRAHEM - administration blood into the circulation system by using of intravenous catheters and cannulas

Extension Line for Single Use: CHIRALINE - connection and extension infusion or transfusion sets for administration liquids or blood into the circulation system by using of intravenous catheter and cannula

Mandrin for Single Use: CHIRAFLEX - long term closure of the intravascular catheters

Three Way Stop Cock for Single Use: CHIRAWAY - administration of fluids and drugs into the human circulating system – to provide access into the peripheral vascular systems through I.V. Cannula for administration of two fluids or drugs at the same time

Stopper for Single Use: CHIRAPLUS - closure of Luer Lock connectors

Port for Single Use: CHIRAPLUS - connection of medical devices, additional input into the system by the drug administration

I.V. Cannula for Single Use: CHIRAFLEX / CHIRAFLEX SAFETY - access into the peripheral vascular system for administration of fluids and drugs and for withdrawal of blood at patient

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 30.09.2022
Valid until 30.09.2027

ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-027

issued for the company

CHIRANA T. Injecta, a.s.

Nám. Dr. A. Schweitzera 194, 916 01 Stará Turá, Slovakia

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of MD number	Description
00	2022-MDR/QS-027	30.09.2022	MDR105_2022, MDR106_2022, MDR107_2022, MDR108_2022, MDR110_2022, MDR111_2022, MDR114_2022, MDR115_2022	Initially granted certification, sampling of technical documentation according to art. 52 (6) MDR.

Notified body · 3EC International · NB 2265 · NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 30.09.2022
Valid until 30.09.2027

Notified Body Confirmation Letter Reference: C627818

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:

Coloplast A/S
Holtedam 1
3050 Humlebæk
Denmark

SRN Number: DK-MF-000025526

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, 2023.09.20

For the issuing office:
DNV Product Assurance AS – Notified Body 2460

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
Biatain Ibu Non-Adhesive foam dressing 57089322853047J	Class III	NA	10000410282-PA-NA-DNK NB Number: NB 2460 EC Design Examination Certificate no: 10000410284-PA-NA-DNK
Biatain Ibu Soft-Hold foam dressing 57089322853057L	Class III	NA	10000410282-PA-NA-DNK NB Number: NB 2460 EC Design Examination Certificate no: 10000410284-PA-NA-DNK
InterDry wicking fabric 57089322853167R	Class III	NA	10000410282-PA-NA-DNK NB Number: NB 2460 EC Design Examination Certificate no.: 10000423479-PA-NA-DNK
Comfeel Plus hydrocolloid dressing 57089322853067N	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Comfeel Plus Transparent hydrocolloid dressing 57089322853077Q	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Comfeel Plus Contour hydrocolloid dressing	Class IIb	NA	10000410282-PA-NA-DNK

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
57089322853097U			NB Number: NB 2460
Biatain Super Adhesive dressing 57089322853117F	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Biatain Super Non-Adhesive dressing 57089322853107D	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Biatain Adhesive foam dressing 57089322852988G	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Biatain Non-Adhesive foam dressing 57089322852978E	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Biatain Silicone foam dressing 57089322853027E	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Biatain Silicone Lite foam dressing 57089322853037G	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Biatain Silicone Non-Border foam dressing 570893260292393Q2	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Biatain Silicone against pressure injuries 57089322853017C	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Purilon Gel 57089322853157P	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Biatain Fiber dressing 57089322853147M	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Conseal Plug 5708932117220516H4	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Peristeen Anal Plug and accessories 57089322978619G	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SenSura Mio Baby flex ostomy bag 2-piece open 570893229756497	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SenSura Mio Baby flex ostomy baseplate 570893229760892	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Alprep Pad 57089322853207G	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 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
Assura/Alterna Post op ostomy bag 1-piece sterile 570893229762592	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SenSura Post op ostomy bag 1-piece sterile 57089322976228U	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SenSura drainable ostomy bag 1-piece open sterile 570893299814023VL	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SenSura Mio Post op ostomy bag 1-piece sterile 57089322976208Q	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Coloplast Drainage bag 1-piece open sterile 5708932117046058HZ	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
EasiCath/SureCath Set urinary intermittent drainage catheter with integrated urine bag 57089322978199H	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
EasiCath catheter urinary intermittent drainage catheter 57089322978169B	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Self-Cath urinary intermittent drainage catheter 570893229782296	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SpeediCath Control urinary intermittent drainage catheter 57089322978289J	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SpeediCath Standard urinary intermittent drainage catheter 57089322978269E	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SpeediCath Compact Eve urinary intermittent drainage catheter 57089322978349D	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SpeediCath Compact female/female plus urinary intermittent drainage catheter 57089322978339B	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SpeediCath Compact male urinary intermittent drainage catheter 570893229783197	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SpeediCath Compact Set female urinary intermittent drainage catheter with integrated urine bag	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 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
57089322978369H			
SpeediCath Compact Set Male urinary intermittent drainage catheter with integrated urine bag 57089322978359F	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SpeediCath Flex urinary intermittent drainage catheter 57089322978379K	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SpeediCath Flex Set urinary intermittent drainage catheter with integrated urine bag 5708932117288128LH	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SpeediCath Navi urinary intermittent drainage catheter 57089322978399P	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SpeediCath Soft urinary intermittent drainage catheter 570893261193271PW	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
EasiCath Dilatation urinary intermittent dilatation catheter 57089322978179D	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
EasiCath Luerlock urinary intermittent infusion and drainage catheter 57089322978189F	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Conveen Security+ bedside drainage bag sterile drainable sample port 57089322978919R	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Simpla Plus bedside drainage bag sterile drainable sample port 57089322978929T	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Simpla Profile bedside drainage bag sterile EtO drainable sample port 57089322978939V	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Simpla Profile bedside drainage bag sterile Irradiation drainable sample port 5708932117311270H4	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Simpla S4 bedside drainage bag sterile drainable sample port 5708932297896A3	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Simpla S5 bedside drainage bag sterile drainable sample port	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 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
5708932297897A5			
Conveen Standard combi bag sterile drainable 5708932297899A9	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Conveen Contour leg bag sterile drainable sample port 57089322978709H	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Conveen Security+ leg bag sterile drainable 57089322978749R	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Conveen Security+ leg bag sterile drainable sample port 57089322978739P	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Freedom Triform leg bag sterile drainable sample port 57089322978769V	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Simpla Plus leg bag sterile drainable sample port 57089322978779X	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Simpla Plus Syphon leg bag sterile drainable sample port 57089322978789Z	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Simpla Profile leg bag sterile drainable sample port 57089322978819N	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Titan Inflatable Penile Prosthesis 570893291871755U9	Class IIb	Titan Inflatable Penile Prosthesis	10000410282-PA-NA-DNK NB Number: NB 2460
Titan Inflatable Penile Prosthesis Accessories 5708932110370449FT	Class IIb	Titan Inflatable Penile Prosthesis Accessories	10000410282-PA-NA-DNK NB Number: NB 2460
Genesis Malleable Penile Prosthesis 570893255573908T9	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Virtue Male Sling System 570893255591814T7	Class III	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Aris Introducers 570893255591823T8	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Furlow Insertion Tool 570893255573897TV	Class Ir	Furlow Insertion Tool	N/A - Device did not require a Notified Body certificate under Directives
Rossello Dilator Set	Class Ir	NA	N/A - Device did not

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
570893255573898TX			require a Notified Body certificate under Directives
Brooks Dilator Set 5708932121570220GP	Class Ir	Brooks Dilator Set	N/A - Device did not require a Notified Body certificate under Directives
Hydro X-Flow catheter silicone with hydrogel coating 57089326358899A	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
X-Flow prostatectomy catheter 570893263588898	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Freudenberg introducer 570893263589697	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Connector for tubes 57089326358608J	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Luer connector to syringe PVC 57089326358588X	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Luer lock connector for ureteric catheter to syringe polyamide 57089326358578V	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Tuohy borst adapter 57089326358568T	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Double loop ureteral stent set in polyamide 570893262832628RL	Class IIb Implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Double loop ureteral stent set in polyurethane 570893262832633RD	Class IIb Implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Detour subcutaneous ureteral bypass 57089326358478S	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Guidewire stainless steel without coating 57089326358468Q	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Stainless steel PTFE coated guidewire 57089326358458N	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Percutaneous nephrostomy guidewire 57089326358448L	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Luer connector for urine bag 57089326358648S	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Vortek J percutaneous	Class IIb	NA	10000410282-PA-NA-

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
nephrostomy catheter 57089326358628N			DNK NB Number: NB 2460
Vortek malecot percutaneous nephrostomy catheter 570893262832582RM	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Balloon nephrostomy catheter short term (Silicone nephrostomy balloon catheters) 57089326358498W	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Percutaneous nephrostomy dilator 57089326358518H	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Percutaneous puncture needle 57089326358508F	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Direct puncture set 57089326358538M	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Percutaneous nephrostomy set with simple loop vortek catheter 570893262832546RH	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Dormia No-Tip / N-Stone 570893263586994	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Biosoft duo double loop ureteral stent 57089326358348H	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Biosoft duo multilength hydro-coated ureteral stent 570893262832542R9	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Double loop in rigid polyurethane 57089326358278L	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Double loop in soft polyurethane 57089326358268J	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Double loop ureteral stent in silicone 57089326358298Q	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Double loop ureteral stent silicone hydrogel 57089326358328D	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Double loop ureteral stent in silicone with partial reinforcement 570893263583089	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Double loop ureteral stent in silicone with total reinforcement	Class IIb implantable	NA	10000410282-PA-NA-DNK

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
57089326358318B			NB Number: NB 2460
Single loop ureteral stent 57089326358228A	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Tumor Stent double loop ureteral stent 57089326358258G	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Vortek double loop ureteral stent 57089326358248E	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Vortek hydro-coated double loop ureteral stent with hydrogel coating 57089326358238C	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Non steerable pusher 570893262832532R6	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Non steerable radiopaque pusher 570893262832531R4	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Steerable pusher 570893262832522R3	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Ureteric drainage catheter in neoplex 57089326358368M	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Ureteric drainage catheter in polyamide 57089326358378P	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Floppy tip hydro-coated ureteric catheter 57089326358408C	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Ureteric interventional catheter 57089326358398T	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Ureteric catheter for retrograde uretero-pyelography 57089326358388R	Class Is	Ureteric catheter for retrograde uretero-pyelography	10000410282-PA-NA-DNK NB Number: NB 2460
Retrace ureteral access sheath 57089326358418E	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Ureteral dilator 57089326358428G	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Short term enterocystoplasty catheter 57089326358088G	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Short term uretero-sigmoidostomy catheter	Class IIa	NA	10000410282-PA-NA-DNK

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
57089326358078E			NB Number: NB 2460
Single loop ureterostomy catheter 570893263581083	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Ureterostomy catheter 57089326358098J	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Elefant suction-irrigation device 570893263590085	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Escat transcystic drains in PVC 57089326359058F	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Pedinielli transcystic drains in PVC 57089326359048D	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Coeliodrain for cholangiography 570893263590289	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Delbet drains 57089326359078K	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Multitubular drain silicone 57089326359068H	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Tubular drains silicone 570893262838040RN	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Multi-perforated tubular drain silicone radiopaque 57089326359098P	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Bonee needle for bladder injection 570893263588694	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Neoplex catheters without balloon 570893263587793	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Catheter valve 57089326358768Z	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Folysil silicone catheter 57089326358748V	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Folysil silicone catheter - Long-term 57089326358758X	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Cystodrain supra-pubic drainage set with silicone J tip catheter 57089326358808Q	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Cystodrain supra-pubic puncture set with polyurethane J tip catheter	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 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
570893263588185			
Cystodrain integral set for supra-pubic drainage 570893263588285	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Supraflow supra-pubic drainage set with silicone balloon catheter 570893263588592	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Uristil suprapubic drainage set in silicone 570893263588387	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Bougie neoplex for routine urethral dilation 570893263587997	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Filiform bougie neoplex 570893263587895	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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
NA	NA	NA	NA

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/09/20	C627818	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

EC Certificate

Certificate Number: DGM – 410

This is to certify that the quality system of:

Coloplast A/S
Holtedam 1
3050 Humlebaek
Denmark
has been approved in conformity with the requirements of:

Annex II Full quality assurance system

of Council Directive 93/42/EEC concerning medical devices as amended and transposed into Danish law, excluding Annex II, section 4.

The certificate covers the following activities:

Design, development and manufacture of surgical meshes, guidewires, ostomy, wound and skin care, drainage, surgery, urology, gynaecology and continence care products in class I sterile, class IIa, class IIb and class III

This EC certificate is issued in accordance with Presafe Denmark A/S' terms and conditions cf. Council Directive 93/42/EEC concerning medical devices and entitles the manufacturer to affix the CE mark. The certificate is based on successful audit of the manufacturer. The manufacturer is subject to periodical audits in accordance with the Directive.

Date of issue:	2018-09-21
Expires:	2023-09-21
Initial date of issue:	2003-04-30
Reference:	Aur2a1809v1260f492

Authorized person

For Presafe Denmark A/S

Presafe Denmark A/S
Notified Body, Identification No. 0543
Tuborg Parkvej 8, 2900 Hellerup, Denmark

The following sites are covered by the certificate:

With the following sites in Denmark:

Coloplast A/S
Industrivej 7
7700 Thisted

Coloplast A/S
Holtedam 1 and 3
3050 Humlebaek

Coloplast A/S
Aa. Louis-Hansens Allé 15
Mørdrup
3060 Espergaerde

With the following sites in France:

Coloplast Manufacturing France SAS
Le Pontet, BP89
24203 Sarlat Cedex

Coloplast Manufacturing France SAS
Lieudit La Boursidière
Centre d'Affaires
92350 Le Plessis Robinson

Coloplast Manufacturing France SAS
Madrazès, BP89
24203 Sarlat Cedex

Coloplast Manufacturing France SAS
ZAC du Clotais
2b, Route du Chemin Blanc
91160 Champlan

With the following sites in Hungary:

Coloplast Hungary KFT
Búzavirág út 15
2800 Tatabánya

Coloplast Hungary KFT
Coloplast utca 2
4300 Nyírbátor

Coloplast Hungary KFT
Kerék utca 3
2800 Tatabánya

With the following sites in the USA:

Coloplast Corporation
1601 West River Road North
Minneapolis, MN 55411

Coloplast Manufacturing US, LLC
1601 West River Road North
Minneapolis, MN 55411

Coloplast Manufacturing US, LLC
1940 Commerce Dr.
North Mankato, MN 56003

With the following site in the People's Republic of China:

Coloplast (China) Ltd.
No. 202, Baocheng Rd
Xiangzhou District
Zhuhai 519030

Coloplast (China) Ltd.
No. 18 Pingbei Er Rd.
Nanping Industrial Park
Zhuhai City 519060

Certificate number: DGM – 410
Certificate type: EC Certificate

Date of issue: 2018-09-21
Expires: 2023-09-21
Initial date of issue: 2003-04-30
Reference: Aur2a1809v1260f492

The following product families in class III are covered by the certificate and by Design Examination certificates as specified below:

Antibacterial Foam Dressings (DGM – 529)
Antibacterial Wound Contact Layer (DGM – 530)
Ibu Foam Dressings (DGM – 528)

The following product families in class IIb are covered by the certificate:

Alginate Dressings
Biatain Foam Dressings
Comfeel Wound Dressings
Conseal Ostomy Plugs
Hydrocapillary Dressings
Isorins
Penile Inflatable Implants
Penile Rigidity Implants
Peristeen Anal Plugs
Physiotulle Dressings
Purilon Gel
Surgical Accessories
Surgical meshes
Testicular Prostheses
Urinary Indwelling Catheters
Urinary/Percutaneous Indwelling Catheters
Urinary/Suprapubic Indwelling Catheters
Urological Implants
Vaginal Stents

Certificate number: DGM – 410
Certificate type: EC Certificate

Date of issue: 2018-09-21
Expires: 2023-09-21
Initial date of issue: 2003-04-30
Reference: Aur2a1809v1260f492

The following product families in class IIa are covered by the certificate:

Ostomy Rod
Stone Extractors
Surgical Accessories
Surgical Drainage
Suture/Needle passer
Urinary Indwelling Catheters
Urinary/Percutaneous Indwelling Catheters
Urodynamic Accessories
Urodynamic Catheters
Urological Accessories
Urological Implants

The following sterile product families in class I are covered by the certificate:

Catheter Irrigation Solutions (sterile)
Drainage Bags (sterile)
Ostomy Post-Operative Sets (sterile)
Surgical Accessories (sterile)
Urinary Catheters for Intermittent Use (sterile)
Urine Bags (sterile)
Urological Accessories (sterile)
Urological Catheters (sterile)

Certificate number:	DGM – 410	Date of issue:	2018-09-21
Certificate type:	EC Certificate	Expires:	2023-09-21
		Initial date of issue:	2003-04-30
		Reference:	Aur2a1809v1260f492

EC Certificate

Certificate Number: DGM – 410

Presafe®
A DNV & NEMKO COMPANY

Patvirtiname, kad žemiau nurodytos įmonės kokybės sistema

Coloplast A/S
Holtedam 1
3050 Humlebaek
Danija

atitinka žemiau nurodytos direktyvos reikalavimus

Priedas II pilna kokybės užtikrinimo sistema

Tarybos direktyva 93/42/EEB dėl medicinos priemonių pagal Danijos įstatymų pataisas ir transpozicijas, išskyrus II priedo, 4 skyrių

Sertifikavimo sritis:

Chirurginių tinklelių, pravedėjų, ostomijos, žaizdų ir odos priežiūros, drenavimo, chirurgijos, urologijos, ginekologijos ir inkontinencijos priežiūros produktų kūrimas, vystymas ir gamyba, I klasė sterili, IIa klasė, IIb klasė ir III klasė

CE sertifikatas galioja tol, kol įdiegta kokybės sistema atitinka sukščiau paminėtus reikalavimus, atsižvelgiant į tai, jog įmonė neatliko jokių reikšmingų kokybės sistemos pokyčių be sertifikavimo įstaigos Presafe Denmark A/S sutikimo. CE sertifikavimas išduodamas pagal Presafe Denmark A/S taisykles, taikomas medicininių priemonių sertifikavimui, ir leidžia šio sertifikato savininkui žymėti prekes CE ženklu.

/parašas/	Išleidimo data:	2018-09-21
Heidi Jorgensen	Galioja iki:	2023-09-21
	Pirmoji leidimo data:	2003-04-30
Presafe Denmark A/S	Nuoroda:	aur2a1809v1260f492

Presafe Denmark A/S
Notifikuota įstaiga, identifikacijos Nr. 0543
Tuborg Parkvej 8, 2900 Helleruo, Danija

Šis sertifikatas skirtas ir sekančioms veiklos sritims:

Danijoje:

Coloplast
Industrivej 7
7700 Thisted

Coloplast
Holtedam 1 ir 3
3050 Humlebaek

Coloplast A/S
Aa. Louis-Hansens Alle 15
Mordrup
3060 Espergaerde

Prancūzijoje**:**
Coloplast Manufacturing France SA
Le Pontet, BP89
24203 Sarlat Cedex

Coloplast Manufacturing France SA
Lieaudit La Boursidiere
Centre d'Affaires
92350 Le Plessis Robinson

Coloplast Manufacturing France SA
Madrazes, BP89
24203 Sarlat Cedex

Coloplast Manufacturing France SA
ZAC du Clotais
2b, Route du Chemin Blanc
91160 Champlan

Sertifikato numeris: DGM-410
Sertifikato rūšis: CE sertifikatas

Išleidimo data: 2018-09-21
Galioja iki: 2023-09-21
Pirminio leidimo data: 2003-04-30
Nuoroda: aur2a1809v1260f492

Vengrijoje:

Coloplast Vengrija KFT
Búzavirág út 15
2800 Tatabánya

Coloplast Vengrija KFT
Coloplast utca 2
4300 Nyirbátor

Coloplast Vengrija KFT
Barina g. 1
2890 Tata

JAV:

Coloplast Corporation
1601 West River Road North
Mineapolis, MN 55411

Coloplast Manufacturing US, LLC
1601 West River Road North
Mineapolis, MN 55411

Coloplast Manufacturing US, LLC
1940 Commerce Dr.
North Mankato, MN 56003

Kinija:

Coloplast (Kinija) Ltd.
Bao Cheng Rd.
Zhuhai Free Trade Zone
Zhuhai 519030 Guangdong

Coloplast (Kinija) Ltd.
3F, Nr. 1, Bldg, Honda Road
Nanping Industrial park
Zhuhai miestas 519060

Sertifikatas taikomas šioms III klasės medicininėms priemonės:

Antibakteriniai putų tvarsčiai (DGM – 529)
Antibakteriniai pleistrai žaizdoms (DGM – 530)
IBU putų tvarsčiai (DGM – 528)

Sertifikato numeris: DGM-410
Sertifikato rūšis: CE sertifikatas

Išleidimo data: 2018-09-21
Galioja iki: 2023-09-21
Pirminio leidimo data: 2003-04-30
Nuoroda: aur2a1809v1260f492

Sertifikatas taikomas šioms IIb klasės medicininėms priemonėms:

Alginate tvarsčiai
Biatain putų tvarsčiai
Comfeel žaizdų tvarsčiai
Conseal ostomijos tamponai
Hidrokapiliariniai tvarsčiai
Izorinai
Varpos implantai
Implantai varpos tvirtumui
Peristeen analiniai tamponai
Physiotulle tvarsčiai
Purilon gelis
Chirurginiai priedai
Chirurginiai tinkleliai
Sėklidžių protezai
Šlapimo kateteriai
Šlapimo/perkutaniniai kateteriai
Šlapimo/suprapubiniai kateteriai
Urologiniai implantai
Vaginaliniai stentai

Sertifikato numeris: DGM-410
Sertifikato rūšis: CE sertifikatas

Išleidimo data: 2018-09-21
Galioja iki: 2023-09-21
Pirminio leidimo data: 2003-04-30
Nuoroda: aur2a1809v1260f492

Sertifikatas taikomas šioms IIa klasės medicininėms priemonėms:

Ostomijos lazdelė
Akmenų ištraukėjai
Chirurginiai priedai
Chirurginio drenavimo priemonės
Siūlų/adatų pravedėjai
Šlapimo kateteriai
Šlapimo/perkutaniniai kateteriai
Urodinaminiai priedai
Urodinaminiai kateteriai
Urologiniai priedai
Urologiniai implantai

Sertifikatas taikomas šioms I klasės medicininėms priemonėms:

Kateterių praplovimo tirpalai (sterilūs)
Drenavimo maišeliai (sterilūs)
Ostomijos pooperaciniai rinkiniai (sterilūs)
Chirurginiai priedai (sterilūs)
Šlapimo kateteriai protarpiniam naudojimui (sterilūs)
Šlapimo maišeliai (sterilūs)
Urologiniai priedai (sterilūs)
Urologiniai kateteriai (sterilūs)

Sertifikato numeris: DGM-410
Sertifikato rūšis: CE sertifikatas

Išleidimo data: 2018-09-21
Galioja iki: 2023-09-21
Pirminio leidimo data: 2003-04-30
Nuoroda: aur2a1809v1260f492

DNV Product Assurance AS
Medical Devices
Veritasveien 3, 1363 Høvik
Postal address: P.O. Box 116, N-1300 Sandvika, Norway
Tel: +47 67 57 88 00
Enterprise No: NO 997 067 401

Date:
30 August 2023

Dear Hassan

We confirm that the products listed in table 1 will be continued to be under MDD surveillance by DNV according to the framework agreement signed 2021-03-26 until the certificate expiration on 26 May 2024 according to Regulation (EU) 2023 / 607.

Sincerely
for DNV Product Assurance AS

Certification Manager

Cc: DNV Business Assurance Korea office

Table 1: List of Coloplast devices which will not upgrade under MDR.

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**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 (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
Easivac system for collecting pieces of tissue after TURP 570893263589799	Class Is	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
CystoCare post operative urine bags 57089329106137D	Class Is	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Prostatectomy catheter siliconised semi-rigid latex 570893263588796	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Prostaflow prostatectomy catheter 57089326358908T	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Prostatectomy catheter siliconised	Class IIa	NA	1000041028 2-PA-NA-	Expiry date: 21	26 May 2024

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**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 (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
reinforced latex 57089326358918V			DNK NB number: NB 2460 DNV Product Assurance AS	Sep 2023	
Prostatic special catheters – latex 5708932115290438JL	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Urospiral 2 - Prostatic stent	Class IIb implantable	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
In-Ka for Percutaneous Nephrolithotomy 57089326358668W	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
In-Ka ureteral balloon dilatation catheter 57089326358678Y	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance	Expiry date: 21 Sep 2023	26 May 2024

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**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 (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
			AS		
Conical connector for ureteric catheter to urine bag latex 57089326358598Z	Class Is	TPE connectors 5708932122590763 K9 (Class Is)	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Orchestra hydrophilic guidewire 57089326358438J	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Drain for nephrostomy with malleable blunt needle (PCN Drainage - Gil-Vernet) 57089326358618L	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Amplatz sheath 57089326358658U	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Vortek percutaneous nephrostomy catheter cumming-malecot	Class IIb	NA	1000041028 2-PA-NA-DNK NB number:	Expiry date: 21 Sep 2023	26 May 2024

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**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 (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
			NB 2460 DNV Product Assurance AS		
Percutaneous nephrostomy set with silicone balloon catheter (Kolibri - Silicone nephrostomy balloon catheter set) 57089326358548P	Class IIb	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Dormia stone extractor 570893263586892	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Steerable radiopaque pusher	Class IIa	ORX tip steerable radiopaque pusher	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Dormia biliary stone extractor 570893263590187	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Kehr T-drain latex 57089326359038B	Class IIa	NA	1000041028 2-PA-NA-	Expiry date: 21	26 May 2024

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**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 (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
& Abdominal irrigation-lavage drain 57089326359088M & Drain with controlled aspiration 570893263591088 & Flat suction drain silicone 57089326359118A			DNK NB number: NB 2460 DNV Product Assurance AS	Sep 2023	
Bulb for drain 57089326359128C	Class Is	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Folatex silicone coated latex urinary catheter (Folatex soft latex catheter) 57089326358718P	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Releen InLine urinary indwelling drainage catheter 570893229781599	Class IIb	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Multi-organ procurement catheter	Class IIa	NA	1000041028 2-PA-NA-DNK	Expiry date: 21 Sep 2023	26 May 2024

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**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 (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
57089326358999D			NB number: NB 2460 DNV Product Assurance AS		
DIABOLO® Urethral Stent	Class IIb implantable	NA	100004102828-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Foley catheters - Semi-rigid latex: Foley catheter straight tip 57089326358728R & Foley catheter coudé tip 57089326358738T	Class IIb	NA	100004102828-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Soft latex Rusch	Class IIa	NA	100004102828-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Biosoft minute stent	Class IIb implantable	NA	100004102828-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**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 (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
Pezzer & Malécot Catheters	Class IIb	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
S.P.E.C. 10® Emergency supra-pubic set	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
PVC Bougies	Class Is	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Urodynamic catheters	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Cobra Single Use Biopsy Gun	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460	Expiry date: 21 Sep 2023	26 May 2024

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**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 (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
			DNV Product Assurance AS		
Gastro-Intestinal Tubes	Class IIb	NA	100004102828-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Oesophageal Bougies	Class Is	NA	100004102828-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Larget Rod	Class IIa	NA	100004102828-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Biatain Soft-Hold foam dressing	Class IIb	NA	100004102828-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Comfeel Plus Transparent hydrocolloid	Class IIb	NA	100004102828-PA-NA-DNK	Expiry date: 21 Sep 2023	26 May 2024

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**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 (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
dressing old generation			NB number: NB 2460 DNV Product Assurance AS		
Comfeel Plus hydrocolloid dressing old generation	Class IIb	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 00364**

Issued To:

ConvaTec Limited
First Avenue
Deeside Industrial Park
Deeside
Flintshire
CH5 2NU
United Kingdom

In respect of:

The design, development and manufacture of sterile wound management dressings (incorporating alginate, hydrogel, foam, fibrous hydrocolloid, porcine gelatin based hydrocolloid and odour-absorbing technologies), sterile medicated wound dressings, sterile wound irrigation devices, sterile ostomy, non-sterile faecal incontinence systems; sterile catheters, cannulae and accessories (excluding intravascular, epidural and spinal); sterile suction sets, sterile gastroenterology tubing; sterile and non-sterile urinary drainage systems and accessories; sterile wound drainage systems, sterile surgical disposables; battery powered negative pressure wound therapy pumps and dressings.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **1994-12-09** Date: **2018-10-23** Expiry Date: **2023-10-20**

...making excellence a habit.™

ConvaTec Limited
First Avenue
Deeside Industrial Park
Deeside
Flintshire
CH5 2NU
United Kingdom

04 July 2023

Notified Body Confirmation Letter
Reference: EU2023-607/651311

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, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** 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:

ConvaTec Limited
First Avenue
Deeside Industrial Park
Deeside
Flintshire
CH5 2NU
United Kingdom

SRN Number (if available): GB-MF-000001770

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 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 the 20 Mar 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 (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)

On behalf of BSI Group The Netherlands B.V.,

Debbie Addison

Digitally signed by Debbie Addison
Date: 2023.07.04 11:46:29 +01'00'

Debbie Addison

BSI Scheme Manager

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
Aquacel Surgical Cover Dressing Basic UDI-DI: 768455AWC00203C	Class III	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797 MDD Certificate #2: CE 00380 Expiry date: 26/05/2024 NB#: 2797
Duoderm Extra Thin Basic UDI-DI: 768455AWC00303F	Class III	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797 MDD Certificate #2: CE 00380 Expiry date: 26/05/2024 NB#: 2797
Duoderm Signal Basic UDI-DI: 768455AWC00313H	Class III	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797 MDD Certificate #2: CE 00380 Expiry date: 26/05/2024 NB#: 2797
Duoderm CGF Basic UDI-DI: 768455AWC00323K	Class III	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797 MDD Certificate #2: CE 00380 Expiry date: 26/05/2024 NB#: 2797
Duoderm CGF Border Basic UDI-DI: 768455AWC00293W	Class III	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797 MDD Certificate #2: CE 00380 Expiry date: 26/05/2024 NB#: 2797
Aquacel Foam Basic UDI-DI: 768455AWC00063J	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797

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
Aquacel Foam Pro Basic UDI-DI: 768455AWC00073L	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797
Aquacel Extra & WSF Basic UDI-DI: 768455AWC00213E	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797
Carboflex Basic UDI-DI: 768455AWC00083N	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797
Duoderm Gel Basic UDI-DI: 768455AWC00093Q	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797
ConvaTec Foam Lite Basic UDI-DI: 768455AWC00193T	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797
Kaltostat Basic UDI-DI: 768455AWC00053G	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797
Avelle NPWT Dressing Basic UDI-DI: 768455AWC00033C	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797
Avelle NPWT Pump Basic UDI-DI: 768455AWC00023A	Class IIa	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797
Hydrocolloid Sealing Strips Basic UDI-DI: 768455AWC00163M	Class I device placed on the market in sterile condition	N/A	MDD Certificate #1: CE 56172 Expiry date: 20/10/2023 NB#: 2797
Loop Ostomy Rod Basic UDI-DI: 768455OST0005F5	Class IIa	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797

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	Action
2023/07/04	Initial issue

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 033038 0037 Rev. 00

Manufacturer:

Cook Ireland Limited
O'Halloran Road
National Technology Park
Limerick
IRELAND

Product Category(ies):

Disposable devices and accessories for use in vascular, urological, gastroenterological pulmonary procedures (class IIa and IIb) including catheters, introducers, wires and drainage sets, electrosurgical and non-active instruments, stents and stent grafts, needles, cannulae and connecting tubes. Vascular stents and delivery systems.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 75941443_CN

Valid from: 2020-03-04
Valid until: 2024-05-26

Date, 2020-03-04

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de

KOPIJA

ZLG-BS-244.10.08

Product Service

CE Sertifikatas

Produkto kokybės užtikrinimo sistema
Medicinos prietaisų Direktyva 93/42/EEC, Priedas II, išskyrus (4)
(IIa, IIb ar III klasės prietaisai)

No. G1 033038 0037 Perž. 00

Gamintojas: **Cook Ireland Limited**
O'Halloran kelias
National Technology Park
Limerick
Airija

Produkto kategorija (-os):

Vienkartiniai prietaisai ir jų priedai kraujagyslių, urologijos, gastroenterologijos, plaučių procedūrose (IIa ir IIb klasė), įskaitant kateterius, introdiuserius, vielas ir drenavimo rinkinius, elektrochirurginius ir neaktyvius instrumentus, stentus, stentgraftus, adatas, kaniules ir jungiamuosius vamzdelius. Kraujagyslių stentus ir įvedimo sistemas.

Notifikuotoji įstaiga TUV SUD Product Service GmbH pareiškia, kad anksčiau minėtas gamintojas įdiegė produktų dizaino, gamybos ir galutinio atitinkamų prietaisų patikrinimo kokybės užtikrinimo sistemą, pagal Direktyvos II priedą. Ši kokybės Sistema apima prietaisų periodinių patikrinimų aspektus, kaip nurodyta Direktyvoje. III klasės prietaisų prekybai papildomai yra privalomas Direktyvos II priedo (4) sertifikatas. Žiūrėti pastabas kitoje pusėje.

Ataskaita Nr.: 75941443_CN

Galioja nuo: 2020-03-04
Galioja iki: 2024-05-26

Data, 2020-03-04

Notifikuotosios įstaigos vadovas

Product Service

Add value.
Inspire trust.

TÜV SÜD Product Service GmbH · Ridlerstrasse 65 · 80339 Munich · Germany

Cook Ireland Limited
O'Halloran Road
National Technology Park
LIMERICK
IRELAND

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
33038	713212698 Ruairi McCaul	+353 (0) 860 755843 ruairi.mccaul@tuvsud.com	-	2024-01-26	1 of 24

TÜV SÜD Product Service GmbH
Confirmation Letter

CL 033038 0059 Rev. 00

Reference: **713212698 | 713233811 | 713254205 | 713255917 | 713260952 | 713222487 | 713222510 | 713228654 | 713252400 | 713258121 | 713260959 | 713260960 | 713260963 | 713261373 | 713270171 | 713270207**

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 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have 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 above stated manufacturer with the following SRN Number:

SRN Number: IE-MF-000001530

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 TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.

Product Service

- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If 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.

The transition timelines in accordance Article 120 (3) of MDR 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, 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 (except 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, 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)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 033038 0059 Rev. 00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-01-26

TÜV SÜD Product Service GmbH
Medical and Health Services

TÜV SÜD Product Service GmbH
Medical and Health Services

Assessment Responsible (CARE)

Reviewer

Product Service

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH 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 during application review)	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
BUDI-DI: **0827002CIRL202007067008E6** **Article Numbers:** RMS-060012-R RMS-060014-R RMS-060016-R RMS-060018-R RMS-060020-R RMS-060022-R RMS-060024-R RMS-060026-R RMS-060028-R RMS-060030-R	☐ Class III ☒ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BUDI-DI: **0827002CIRL202007008009CD** **Article Numbers:** USI-500 USI-500-B USI-500-B-T USI-500-LP USI-500-R USI-500-RPC USI-512 USI-512-CE USI-512-LP USI-512-RPC USI-514 USI-514-RPC USI-516 USI-516-LP USI-518 USI-520 USI-520-B USI-520-LP USI-520-R USI-520-RPC USI-522 USI-522-B USI-522-CE USI-522-LP USI-522-R USI-522-RPC USI-524 USI-524-B USI-524-CE USI-524-LP USI-524-R USI-524-RPC USI-526 USI-526-B USI-526-CE USI-526-CE-B USI-526-CE-LP USI-526-CE-R USI-526-LP USI-526-R USI-526-RPC USI-526-RPC-LP	☐ Class III ☒ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
USI-528 USI-528-B USI-528-CE USI-528-CE-B USI-528-LP USI-528-R USI-528-RPC USI-530 USI-530-B USI-530-LP USI-530-R USI-530-RPC USI-600 USI-600-B USI-600-B-T USI-600-CE USI-600-LP USI-600-R USI-600-RPC USI-600-RPC-T USI-600-R-T USI-600-T USI-612 USI-614 USI-614-RPC-T USI-616 USI-616-RPC USI-618 USI-620 USI-620-B USI-620-LP USI-620-R USI-620-RPC USI-622 USI-622-B USI-622-CE USI-622-LP USI-622-R USI-622-RPC USI-622-RPC-LP USI-624 USI-624-B USI-624-CE USI-624-CE-LP USI-624-CE-R USI-624-LP USI-624-R USI-624-RPC USI-624-RPC-LP USI-624-RPC-T USI-624-R-T USI-624-T USI-626 USI-626-B USI-626-CE USI-626-CE-B USI-626-CE-LP USI-626-CE-R USI-626-CE-RPC-T USI-626-LP USI-626-R USI-626-RPC USI-626-RPC-LP USI-626-RPC-T USI-626-R-T USI-626-T USI-628 USI-628-B USI-628-CE USI-628-CE-B USI-628-CE-LP USI-628-LP			

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
USI-628-LP-PD USI-628-R USI-628-RPC USI-628-RPC-LP USI-628-RPC-T USI-628-R-T USI-628-T USI-630 USI-630-B USI-630-LP USI-630-R USI-630-RPC USI-700 USI-700-B USI-700-LP USI-700-R USI-700-RPC USI-700-RPC-T USI-700-R-T USI-712 USI-714 USI-716 USI-716-B USI-718 USI-718-P USI-720 USI-720-B USI-720-LP USI-720-R USI-720-RPC USI-722 USI-722-B USI-722-CE USI-722-LP USI-722-P USI-722-R USI-722-RPC USI-724 USI-724-B USI-724-CE USI-724-LP USI-724-P USI-724-R USI-724-RPC USI-724-RPC-LP USI-724-RPC-T USI-724-R-T USI-726 USI-726-B USI-726-CE USI-726-CE-B USI-726-CE-LP USI-726-LP USI-726-P USI-726-R USI-726-RPC USI-726-RPC-LP USI-726-RPC-T USI-726-R-T USI-728 USI-728-B USI-728-CE USI-728-CE-B USI-728-CE-LP USI-728-LP USI-728-LP-PD USI-728-P USI-728-R USI-728-RPC USI-728-RPC-LP USI-728-RPC-T USI-728-R-T			

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
USI-728-T USI-730 USI-730-B USI-730-LP USI-730-R USI-730-RPC USI-800 USI-800-B USI-800-R USI-800-R-P USI-800-RPC USI-822 USI-822-B USI-822-R USI-822-RPC USI-824 USI-824-B USI-824-CE USI-824-R USI-824-RPC USI-826 USI-826-B USI-826-CE USI-826-R USI-826-RPC USI-828 USI-828-B USI-828-CE USI-828-R USI-828-RPC USI-830 USI-830-B USI-830-R USI-830-RPC			
BUDI-DI: **0827002CIRL202007020003AX** **Article Numbers:** GEPD-10-12 GEPD-10-15 GEPD-10-3 GEPD-10-5 GEPD-10-7 GEPD-10-9 GEPD-11.5-6 GEPD-11.5-8 GEPD-11.5-10 GEPD-11.5-12 GEPD-3-10 GEPD-3-11 GEPD-3-12 GEPD-3-13 GEPD-3-14 GEPD-3-15 GEPD-3-3 GEPD-3-4 GEPD-3-5 GEPD-3-6 GEPD-3-7 GEPD-3-8 GEPD-3-9 GEPD-5-10 GEPD-5-11 GEPD-5-12 GEPD-5-13 GEPD-5-14 GEPD-5-15 GEPD-5-2	☐ Class III ☒ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
GEPD-5-3 GEPD-5-4 GEPD-5-5 GEPD-5-6 GEPD-5-7 GEPD-5-8 GEPD-5-9 GEPD-7-10 GEPD-7-11 GEPD-7-12 GEPD-7-13 GEPD-7-14 GEPD-7-15 GEPD-7-3 GEPD-7-4 GEPD-7-5 GEPD-7-6 GEPD-7-7 GEPD-7-8 GEPD-7-9 GEPD-8.5-12 GEPD-8.5-3 GEPD-8.5-5 GEPD-8.5-7 GEPD-8.5-9 GPDS-5-15 GPDS-5-2 GPDS-5-12 GPDS-5-3 GPDS-5-5 GPDS-5-7 GPDS-5-9 GPDS-7-3 GPDS-7-12 GPDS-7-5 GPDS-7-7 GPDS-7-9 GPSO-7-20 GPSO-10-2 GPSO-10-10 GPSO-10-12 GPSO-10-15 GPSO-10-3 GPSO-10-5 GPSO-10-7 GPSO-10-9 GPSO-3-2 GPSO-3-10 GPSO-3-11 GPSO-3-12 GPSO-3-13 GPSO-3-14 GPSO-3-15 GPSO-3-3 GPSO-3-4 GPSO-3-5 GPSO-3-6 GPSO-3-7 GPSO-3-8 GPSO-3-9 GPSO-4-2 GPSO-4-5 GPSO-4-7 GPSO-4-9 GPSO-5-2 GPSO-5-9 GPSO-5-10 GPSO-5-11 GPSO-5-12 GPSO-5-13 GPSO-5-14 GPSO-5-15			

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
GPSO-5-18 GPSO-5-3 GPSO-5-4 GPSO-5-5 GPSO-5-6 GPSO-5-7 GPSO-5-8 GPSO-6-2 GPSO-6-3 GPSO-6-5 GPSO-6-7 GPSO-6-9 GPSO-6-12 GPSO-6-15 GPSO-7-2 GPSO-7-10 GPSO-7-11 GPSO-7-12 GPSO-7-13 GPSO-7-14 GPSO-7-15 GPSO-7-18 GPSO-7-3 GPSO-7-4 GPSO-7-5 GPSO-7-6 GPSO-7-7 GPSO-7-8 GPSO-7-9 GPSO-8.5-12 GPSO-8.5-15 GPSO-8.5-3 GPSO-8.5-5 GPSO-8.5-7 GPSO-8.5-9 GPSOS-5-2 GPSOS-5-3 GPSOS-5-4 GPSOS-5-5 GPSOS-5-7 GPSOS-5-9 GPSOS-5-12 GPSOS-5-15 GPSOS-7-2 GPSOS-7-3 GPSOS-7-5 GPSOS-7-7 GPSOS-7-9 GPSOS-7-10 GPSOS-7-12 GPSOS-7-15 SPSOF-10-10 SPSOF-10-12 SPSOF-10-15 SPSOF-10-3 SPSOF-10-4 SPSOF-10-5 SPSOF-10-6 SPSOF-10-7 SPSOF-10-8 SPSOF-4-2 SPSOF-4-4 SPSOF-4-6 SPSOF-4-8 SPSOF-4-10 SPSOF-4-12 SPSOF-4-15 SPSOF-4-18 SPSOF-5-9 SPSOF-5-10 SPSOF-5-11 SPSOF-5-12			

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
SPSOF-5-15 SPSOF-5-2 SPSOF-5-2.5 SPSOF-5-3 SPSOF-5-4 SPSOF-5-5 SPSOF-5-6 SPSOF-5-7 SPSOF-5-8 SPSOF-6-2 SPSOF-6-2.5 SPSOF-6-4 SPSOF-6-6 SPSOF-6-8 SPSOF-6-10 SPSOF-6-12 SPSOF-6-15 SPSOF-7-10 SPSOF-7-11 SPSOF-7-12 SPSOF-7-15 SPSOF-7-16 SPSOF-7-18 SPSOF-7-2 SPSOF-7-2.5 SPSOF-7-3 SPSOF-7-4 SPSOF-7-5 SPSOF-7-6 SPSOF-7-7 SPSOF-7-8 SPSOF-7-9 SPSOF-8.5-10 SPSOF-8.5-12 SPSOF-8.5-7 SPSOS-3-10-N SPSOS-3-12-N SPSOS-3-18-N SPSOS-3-4-N SPSOS-3-6-N SPSOS-3-8-N SPSOS-5-3 SPSOS-5-5 SPSOS-5-7 SPSOS-7-3 SPSOS-7-5 ZEPDF-5-9 ZEPDF-7-9 ZEPDF-5-10 ZEPDF-5-12 ZEPDF-5-2 ZEPDF-5-4 ZEPDF-5-5 ZEPDF-5-6 ZEPDF-5-7 ZEPDF-5-8 ZEPDF-7-10 ZEPDF-7-12 ZEPDF-7-15 ZEPDF-7-2 ZEPDF-7-4 ZEPDF-7-5 ZEPDF-7-6 ZEPDF-7-7 ZEPDF-7-8 ZEPDS-5-10 ZEPDS-5-12 ZEPDS-5-2 ZEPDS-5-4 ZEPDS-5-6 ZEPDS-5-8 ZEPDS-7-10			

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
ZEPDS-7-12 ZEPDS-7-4 ZEPDS-7-6 ZEPDS-7-8 ZPSOF-5-10 ZPSOF-5-12 ZPSOF-5-15 ZPSOF-5-2 ZPSOF-5-3 ZPSOF-5-4 ZPSOF-5-5 ZPSOF-5-6 ZPSOF-5-7 ZPSOF-5-8 ZPSOF-5-9 ZPSOF-7-10 ZPSOF-7-12 ZPSOF-7-15 ZPSOF-7-4 ZPSOF-7-6 ZPSOF-7-7 ZPSOF-7-8 ZPSOF-7-2 ZPSOF-7-9 ZPSOS-5-12 ZPSOS-5-3 ZPSOS-5-5 ZPSOS-5-7 ZPSOS-5-9 ZPSOS-7-10 ZPSOS-7-12 ZPSOS-7-4 ZPSOS-7-6 ZPSOS-7-25-NP ZPSOS-7-8 JPWS-8.5-10 JPWS-8.5-22 JPWS-8.5-12 JPWS-8.5-14 JPWS-8.5-16 JPWS-8.5-18 JPWS-8.5-20 JPWS-10-10 JPWS-10-12 JPWS-10-14 JPWS-10-16 JPWS-10-18 JPWS-10-20 JPWS-10-8 JPWS-8.5-8 JPWS-10-22 GPSO-SF-5-3 GPSO-SF-5-5 GPSO-SF-5-7 GPSO-SF-5-9 GPSO-SF-5-12 GPSOS-SF-5-3 GPSOS-SF-5-5 GPSOS-SF-5-7 GPSOS-SF-5-9 GPSOS-SF-5-12			

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
BUDI-DI: **0827002CIRL202009051015DG** **Article Numbers:** ZVT7-35-80-14-6.0 ZVT7-35-80-14-10.0 ZVT7-35-80-14-14.0 ZVT7-35-80-16-6.0 ZVT7-35-80-16-10.0 ZVT7-35-80-16-14.0 ZVT7-35-120-14-6.0 ZVT7-35-120-14-10.0 ZVT7-35-120-14-14.0 ZVT7-35-120-16-6.0 ZVT7-35-120-16-10.0 ZVT7-35-120-16-14.0	☐ Class III ☒ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BUDI-DI: **0827002CIRL202011049017BC** **Article Numbers:** EVO-22-27-12-D EVO-22-27-6-D EVO-22-27-9-D	☐ Class III ☒ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BUDI-DI: **0827002CIRL2020110500249M** **Article Numbers:** ZIB6-40-8-4.0 ZIB6-40-8-6.0 ZIB6-40-8-8.0 ZIB6-40-9-4.0 ZIB6-40-9-6.0 ZIB6-40-9-8.0 ZIB6-40-10-4.0 ZIB6-40-10-6.0 ZIB6-40-10-8.0 ZIB6-40-12-4.0 ZIB6-40-12-6.0 ZIB6-40-12-8.0 ZIB6-40-14-4.0 ZIB6-40-14-6.0 ZIB6-40-14-8.0 ZIB6-40-6-4.0 ZIB6-40-6-6.0 ZIB6-40-6-8.0	☐ Class III ☒ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BUDI-DI: **0827002CIRL202011055020AG** **Article Numbers:** ZFV6-125-5-2.0 ZFV6-125-5-3.0	☐ Class III ☒ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted)	☒ N/A or	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
ZFV6-125-5-4.0 ZFV6-125-5-6.0 ZFV6-125-5-8.0 ZFV6-125-5-10.0 ZFV6-125-5-12.0 ZFV6-125-5-14.0 ZFV6-125-5-17.0 ZFV6-125-6-2.0 ZFV6-125-6-3.0 ZFV6-125-6-4.0 ZFV6-125-6-6.0 ZFV6-125-6-8.0 ZFV6-125-6-10.0 ZFV6-125-6-12.0 ZFV6-125-6-14.0 ZFV6-125-7-2.0 ZFV6-125-7-3.0 ZFV6-125-7-4.0 ZFV6-125-7-6.0 ZFV6-125-7-8.0 ZFV6-125-7-10.0 ZFV6-125-7-12.0 ZFV6-125-7-14.0 ZFV6-125-8-2.0 ZFV6-125-8-3.0 ZFV6-125-8-4.0 ZFV6-125-8-6.0 ZFV6-125-8-8.0 ZFV6-125-8-10.0 ZFV6-125-8-12.0 ZFV6-125-8-14.0 ZFV6-125-9-2.0 ZFV6-125-9-3.0 ZFV6-125-9-4.0 ZFV6-125-9-6.0 ZFV6-125-9-8.0 ZFV6-125-9-10.0 ZFV6-125-9-12.0 ZFV6-125-9-14.0 ZFV6-125-10-2.0 ZFV6-125-10-3.0 ZFV6-125-10-4.0 ZFV6-125-10-6.0 ZFV6-125-10-8.0 ZFV6-125-10-10.0 ZFV6-125-10-12.0 ZFV6-125-10-14.0 ZFV6-125-5-20.0 ZFV6-125-6-17.0 ZFV6-125-6-20.0 ZFV6-125-7-17.0 ZFV6-125-7-20.0 ZFV6-125-8-17.0 ZFV6-125-8-20.0 ZFV6-80-5-2.0 ZFV6-80-5-3.0 ZFV6-80-5-4.0 ZFV6-80-5-6.0 ZFV6-80-5-8.0 ZFV6-80-5-10.0 ZFV6-80-5-12.0 ZFV6-80-5-14.0 ZFV6-80-6-2.0 ZFV6-80-6-3.0 ZFV6-80-6-4.0 ZFV6-80-6-6.0 ZFV6-80-6-8.0 ZFV6-80-6-10.0 ZFV6-80-6-12.0 ZFV6-80-6-14.0 ZFV6-80-7-2.0 ZFV6-80-7-3.0	☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: N\A	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
ZFV6-80-7-4.0 ZFV6-80-7-6.0 ZFV6-80-7-8.0 ZFV6-80-7-10.0 ZFV6-80-7-12.0 ZFV6-80-7-14.0 ZFV6-80-8-2.0 ZFV6-80-8-3.0 ZFV6-80-8-4.0 ZFV6-80-8-6.0 ZFV6-80-8-8.0 ZFV6-80-8-10.0 ZFV6-80-8-12.0 ZFV6-80-8-14.0 ZFV6-80-9-2.0 ZFV6-80-9-3.0 ZFV6-80-9-4.0 ZFV6-80-9-6.0 ZFV6-80-9-8.0 ZFV6-80-9-10.0 ZFV6-80-9-12.0 ZFV6-80-9-14.0 ZFV6-80-10-10.0 ZFV6-80-10-12.0 ZFV6-80-10-14.0 ZFV6-80-10-2.0 ZFV6-80-10-3.0 ZFV6-80-10-4.0 ZFV6-80-10-6.0 ZFV6-80-10-8.0 ZFV6-80-5-17.0 ZFV6-80-5-20.0 ZFV6-80-6-17.0 ZFV6-80-6-20.0 ZFV6-80-7-17.0 ZFV6-80-8-17.0 ZFV6-80-8-20.0 ZFV6-80-7-20.0			
BUDI-DI: **0827002CIRL202011056021AR** **Article Numbers:** ZIV5-80-4-2.0 ZIV5-80-4-3.0 ZIV5-80-4-4.0 ZIV5-80-4-6.0 ZIV5-80-4-8.0 ZIV5-80-5-2.0 ZIV5-80-5-3.0 ZIV5-80-5-4.0 ZIV5-80-5-6.0 ZIV5-80-5-8.0 ZIV5-80-6-2.0 ZIV5-80-6-3.0 ZIV5-80-6-4.0 ZIV5-80-6-6.0 ZIV5-80-6-8.0 ZIV5-80-7-2.0 ZIV5-80-7-3.0 ZIV5-80-7-4.0 ZIV5-80-7-6.0 ZIV5-80-7-8.0 ZIV5-80-8-2.0 ZIV5-80-8-3.0 ZIV5-80-8-4.0 ZIV5-80-8-6.0 ZIV5-80-8-8.0 ZIV5-80-9-2.0 ZIV5-80-9-3.0 ZIV5-80-9-4.0	☐ Class III ☒ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
ZIV5-80-9-6.0 ZIV5-80-9-8.0 ZIV5-80-10-2.0 ZIV5-80-10-3.0 ZIV5-80-10-4.0 ZIV5-80-10-6.0 ZIV5-80-10-8.0 ZIV5-125-4-2.0 ZIV5-125-4-3.0 ZIV5-125-4-4.0 ZIV5-125-4-6.0 ZIV5-125-4-8.0 ZIV5-125-5-2.0 ZIV5-125-5-3.0 ZIV5-125-5-4.0 ZIV5-125-5-6.0 ZIV5-125-5-8.0 ZIV5-125-6-2.0 ZIV5-125-6-3.0 ZIV5-125-6-4.0 ZIV5-125-6-6.0 ZIV5-125-6-8.0 ZIV5-125-7-2.0 ZIV5-125-7-3.0 ZIV5-125-7-4.0 ZIV5-125-7-6.0 ZIV5-125-7-8.0 ZIV5-125-8-2.0 ZIV5-125-8-3.0 ZIV5-125-8-4.0 ZIV5-125-8-6.0 ZIV5-125-8-8.0 ZIV5-125-9-2.0 ZIV5-125-9-3.0 ZIV5-125-9-4.0 ZIV5-125-9-6.0 ZIV5-125-9-8.0 ZIV5-125-10-2.0 ZIV5-125-10-3.0 ZIV5-125-10-4.0 ZIV5-125-10-6.0 ZIV5-125-10-8.0 ZIV6-80-5-2.0 ZIV6-80-5-3.0 ZIV6-80-5-4.0 ZIV6-80-5-6.0 ZIV6-80-5-8.0 ZIV6-80-6-2.0 ZIV6-80-6-3.0 ZIV6-80-6-4.0 ZIV6-80-6-6.0 ZIV6-80-6-8.0 ZIV6-80-7-2.0 ZIV6-80-7-3.0 ZIV6-80-7-4.0 ZIV6-80-7-6.0 ZIV6-80-7-8.0 ZIV6-80-8-2.0 ZIV6-80-8-3.0 ZIV6-80-8-4.0 ZIV6-80-8-6.0 ZIV6-80-8-8.0 ZIV6-80-9-2.0 ZIV6-80-9-3.0 ZIV6-80-9-4.0 ZIV6-80-9-6.0 ZIV6-80-9-8.0 ZIV6-80-10-2.0 ZIV6-80-10-3.0 ZIV6-80-10-4.0 ZIV6-80-10-6.0 ZIV6-80-10-8.0			

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
ZIV6-80-12-3.0 ZIV6-80-12-4.0 ZIV6-80-12-6.0 ZIV6-80-12-8.0 ZIV6-80-14-3.0 ZIV6-80-14-4.0 ZIV6-80-14-6.0 ZIV6-80-14-8.0 ZIV6-125-5-2.0 ZIV6-125-5-3.0 ZIV6-125-5-4.0 ZIV6-125-5-6.0 ZIV6-125-5-8.0 ZIV6-125-6-2.0 ZIV6-125-6-3.0 ZIV6-125-6-4.0 ZIV6-125-6-6.0 ZIV6-125-6-8.0 ZIV6-125-7-2.0 ZIV6-125-7-3.0 ZIV6-125-7-4.0 ZIV6-125-7-6.0 ZIV6-125-7-8.0 ZIV6-125-8-2.0 ZIV6-125-8-3.0 ZIV6-125-8-4.0 ZIV6-125-8-6.0 ZIV6-125-8-8.0 ZIV6-125-9-2.0 ZIV6-125-9-3.0 ZIV6-125-9-4.0 ZIV6-125-9-6.0 ZIV6-125-9-8.0 ZIV6-125-10-2.0 ZIV6-125-10-3.0 ZIV6-125-10-4.0 ZIV6-125-10-6.0 ZIV6-125-10-8.0 ZIV6-125-12-3.0 ZIV6-125-12-4.0 ZIV6-125-12-6.0 ZIV6-125-12-8.0 ZIV6-125-14-3.0 ZIV6-125-14-4.0 ZIV6-125-14-6.0 ZIV6-125-14-8.0			
BUDI-DI: **0827002CIRL202011064022AQ** **Article Numbers:** EVO-PC-8-9-6-B EVO-PC-8-9-8-B EVO-PC-10-11-4-B EVO-PC-10-11-6-B EVO-PC-10-11-8-B EVO-FC-8-9-6-B EVO-FC-8-9-8-B EVO-FC-10-11-4-B EVO-FC-10-11-6-B EVO-FC-10-11-8-B	☐ Class III ☒ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BUDI-DI: **0827002CIRL202309008036FP** **Article Numbers:** UFI-522	☐ Class III ☒ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted)	☒ N/A or	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
UFI-524 UFI-526 UFI-528 UFI-530 UFI-622 UFI-624 UFI-626 UFI-628 UFI-630 UFI-722 UFI-724 UFI-726 UFI-728 UFI-822 UFI-824 UFI-826 UFI-828 UFI-500 UFI-600 UFI-700 UFI-522-R UFI-524-R UFI-526-R UFI-528-R UFI-622-R UFI-624-R UFI-626-R UFI-628-R UFI-722-R UFI-724-R UFI-726-R UFI-728-R UFI-822-R UFI-824-R UFI-826-R UFI-828-R UFI-500-R UFI-600-R UFI-700-R UFI-622-B UFI-624-B UFI-626-B UFI-726-B UFI-500-B UFI-600-B UFI-700-B UFI-522-RPC-LP UFI-524-RPC-LP UFI-526-RPC-LP UFI-528-RPC-LP UFI-622-RPC-LP UFI-624-RPC-LP UFI-626-RPC-LP UFI-628-RPC-LP UFI-722-RPC-LP UFI-724-RPC-LP UFI-726-RPC-LP UFI-728-RPC-LP UFI-500-RPC-LP UFI-600-RPC-LP UFI-700-RPC-LP UFI-626-LP UFI-724-LP UFI-726-P UFI-728-P UFI-626-P UFI-628-P UFI-500-LP UFI-600-LP UFI-700-LP	☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: N\A	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
BUDI-DI: **0827002CIRL202011065016B4** **Article Numbers:** EVO-8-9-4-B EVO-8-9-6-B EVO-8-9-8-B EVO-8-9-10-B EVO-10-11-4-B EVO-10-11-6-B EVO-10-11-8-B EVO-10-11-10-B	☐ Class III ☒ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BUDI-DI: **0827002CIRL202011063030AG** **Article Numbers:** ZILBS-635-10-4 ZILBS-635-10-6 ZILBS-635-10-8 ZILBS-635-6-4 ZILBS-635-6-6 ZILBS-635-6-8 ZILBS-635-8-4 ZILBS-635-8-6 ZILBS-635-8-8 ZILBS-635-10-10 ZILBS-635-10-12 ZILBS-635-8-10 ZILBS-635-8-12 ZILBS-635-6-10 ZILBS-635-6-12	☐ Class III ☒ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BUDI-DI: **0827002CIRL202011068027BW** **Article Numbers:** EVO-25-30-10-C EVO-25-30-6-C EVO-25-30-8-C	☐ Class III ☒ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BUDI-DI: **0827002CIRL202011069028C7** **Article Numbers:** EVO-20-25-10-E EVO-20-25-12.5-E EVO-20-25-15-E EVO-20-25-8-E EVO-FC-18-23-10-E EVO-FC-18-23-12-E EVO-FC-18-23-8-E	☐ Class III ☒ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or ☐ Evidence that a competent authority of a Member State

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
EVO-FC-20-25-10-E EVO-FC-20-25-12-E EVO-FC-20-25-8-E	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BUDI-DI: **0827002CIRL202011070029AM** **Article Numbers:** EVO-FC-R-18-23-10-E EVO-FC-R-18-23-12-E EVO-FC-R-18-23-8-E EVO-FC-R-20-25-10-E EVO-FC-R-20-25-12-E EVO-FC-R-20-25-8-E	☐ Class III ☒ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BUDI-DI: **0827002CIRL202007013010B6** **Article Numbers:** OACL-10-5 OACL-10-7 OACL-10-9 OACL-10-12 OACL-10-15 OACL-8.5-5 OACL-8.5-7 OACL-8.5-9 OACL-8.5-12 OACL-8.5-15 OACL-7-5 OACL-7-7 OACL-7-9 OACL-7-12 OACL-7-15 OACL-11.5-5 OACL-11.5-7 OACL-11.5-9 OACL-11.5-12 OACL-11.5-15 OATS-8.5-5 OATS-8.5-7 OATS-8.5-9 OATS-8.5-12 OATS-8.5-15 OATS-10-5 OATS-10-7 OATS-10-9 OATS-10-12 OATS-10-15 OATS-11.5-5 OATS-11.5-7 OATS-11.5-9 OATS-11.5-12 OATS-11.5-15 ZSS-10-1-RB ZSS-10-3-RB ZSS-10-4-RB ZSS-10-5-RB ZSS-10-7-RB ZSS-10-9-RB ZSS-10-10-RB	☐ Class III ☒ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
ZSS-10-12-RB ZSS-10-15-RB CHBS-10-3 CHBS-10-5 CHBS-10-7 CHBS-10-9 CHBS-10-10 CHBS-10-11 CHBS-10-12 CHBS-10-15 CHBS-11.5-5 CHBS-11.5-7 CHBS-11.5-9 CHBS-11.5-10 CHBS-11.5-12 CHBS-11.5-15 CHBS-7-3 CHBS-7-5 CHBS-7-6 CHBS-7-7 CHBS-7-9 CHBS-7-10 CHBS-7-12 CHBS-7-15 CHBS-8.5-5 CHBS-8.5-7 CHBS-8.5-9 CHBS-8.5-12 CHBS-8.5-15 CHBSO-10-3 CHBSO-10-4 CHBSO-10-5 CHBSO-10-6 CHBSO-10-7 CHBSO-10-8 CHBSO-10-9 CHBSO-10-10 CHBSO-10-11 CHBSO-10-12 CHBSO-10-15 CHBSO-10-18 CHBSO-11.5-5 CHBSO-11.5-7 CHBSO-11.5-8 CHBSO-11.5-9 CHBSO-11.5-10 CHBSO-11.5-12 CHBSO-11.5-15 CHBSO-11.5-18 CHBSO-7-4 CHBSO-7-5 CHBSO-7-7 CHBSO-7-9 CHBSO-7-10 CHBSO-7-12 CHBSO-7-15 CHBSO-7-18 CHBSO-8.5-5 CHBSO-8.5-7 CHBSO-8.5-9 CHBSO-8.5-10 CHBSO-8.5-12 CHBSO-8.5-15 CHBSO-8.5-18 CLBS-10-3 CLBS-10-4 CLBS-10-5 CLBS-10-6 CLBS-10-7 CLBS-10-8 CLBS-10-9 CLBS-10-10			

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
CLBS-10-11 CLBS-10-12 CLBS-10-13 CLBS-10-14 CLBS-10-15 CLBS-10-16 CLBS-10-17 CLBS-10-18 CLBS-11.5-3 CLBS-11.5-5 CLBS-11.5-6 CLBS-11.5-7 CLBS-11.5-8 CLBS-11.5-9 CLBS-11.5-10 CLBS-11.5-11 CLBS-11.5-12 CLBS-11.5-13 CLBS-11.5-14 CLBS-11.5-15 CLBS-11.5-16 CLBS-11.5-17 CLBS-11.5-18 CLBS-5-5 CLBS-5-7 CLBS-5-9 CLBS-5-12 CLBS-7-3 CLBS-7-4 CLBS-7-5 CLBS-7-6 CLBS-7-7 CLBS-7-8 CLBS-7-9 CLBS-7-10 CLBS-7-11 CLBS-7-12 CLBS-7-13 CLBS-7-14 CLBS-7-15 CLBS-7-16 CLBS-7-17 CLBS-7-18 CLBS-8.5-3 CLBS-8.5-5 CLBS-8.5-6 CLBS-8.5-7 CLBS-8.5-8 CLBS-8.5-9 CLBS-8.5-10 CLBS-8.5-11 CLBS-8.5-12 CLBS-8.5-13 CLBS-8.5-14 CLBS-8.5-15 CLBS-8.5-16 CLBS-8.5-17 CLBS-8.5-18 CLSO-5-3 CLSO-5-5 CLSO-5-7 CLSO-5-9 CLSO-5-12 CLSO-5-15 CLSO-7-2 CLSO-7-3 CLSO-7-4 CLSO-7-5 CLSO-7-6 CLSO-7-7 CLSO-7-8 CLSO-7-9			

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
CLSO-7-10 CLSO-7-11 CLSO-7-12 CLSO-7-13 CLSO-7-14 CLSO-7-15 CLSO-7-16 CLSO-7-17 CLSO-7-18 CLSO-7-19 CLSO-7-20 CLSO-7-21 CLSO-8.5-3 CLSO-8.5-5 CLSO-8.5-6 CLSO-8.5-7 CLSO-8.5-8 CLSO-8.5-9 CLSO-8.5-10 CLSO-8.5-11 CLSO-8.5-12 CLSO-8.5-13 CLSO-8.5-14 CLSO-8.5-15 CLSO-8.5-16 CLSO-8.5-17 CLSO-8.5-18 CLSO-8.5-20 CLSO-10-2 CLSO-10-3 CLSO-10-4 CLSO-10-5 CLSO-10-6 CLSO-10-7 CLSO-10-8 CLSO-10-9 CLSO-10-10 CLSO-10-11 CLSO-10-12 CLSO-10-13 CLSO-10-14 CLSO-10-15 CLSO-10-16 CLSO-10-17 CLSO-10-18 CLSO-10-19 CLSO-10-20 CLSO-10-21 CLSO-11.5-3 CLSO-11.5-5 CLSO-11.5-6 CLSO-11.5-7 CLSO-11.5-8 CLSO-11.5-9 CLSO-11.5-10 CLSO-11.5-11 CLSO-11.5-12 CLSO-11.5-13 CLSO-11.5-14 CLSO-11.5-15 CLSO-11.5-16 CLSO-11.5-17 CLSO-11.5-18 CLSO-11.5-20 PBS-7-5 PBS-7-7 PBS-7-9 PBS-7-12 PBS-7-15 PBS-8.5-5 PBS-8.5-7 PBS-8.5-9			

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
PBS-8.5-12 PBS-8.5-15 PBS-10-5 PBS-10-7 PBS-10-9 PBS-10-12 PBS-10-15 PBS-11.5-5 PBS-11.5-7 PBS-11.5-9 PBS-11.5-12 PBS-11.5-15 TTSO-10-5 TTSO-10-6 TTSO-10-7 TTSO-10-8 TTSO-10-9 TTSO-10-10 TTSO-10-11 TTSO-10-12 TTSO-10-13 TTSO-10-14 TTSO-10-15 TTSO-11.5-5 TTSO-11.5-6 TTSO-11.5-7 TTSO-11.5-8 TTSO-11.5-9 TTSO-11.5-10 TTSO-11.5-11 TTSO-11.5-12 TTSO-11.5-13 TTSO-11.5-14 TTSO-11.5-15 TTSO-8.5-5 TTSO-8.5-6 TTSO-8.5-7 TTSO-8.5-8 TTSO-8.5-9 TTSO-8.5-10 TTSO-8.5-11 TTSO-8.5-12 TTSO-8.5-13 TTSO-8.5-14 TTSO-8.5-15 ZEBD-10-2 ZEBD-10-3 ZEBD-10-4 ZEBD-10-5 ZEBD-10-6 ZEBD-10-7 ZEBD-10-8 ZEBD-10-9 ZEBD-10-10 ZEBD-10-12 ZEBD-10-15 ZEBD-5-3 ZEBD-5-4 ZEBD-5-5 ZEBD-5-7 ZEBD-5-9 ZEBD-5-10 ZEBD-5-12 ZEBD-5-15 ZEBD-6-4 ZEBD-6-7 ZEBD-6-10 ZEBD-6-12 ZEBD-7-2 ZEBD-7-3 ZEBD-7-4 ZEBD-7-5			

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
ZEBD-7-7 ZEBD-7-6 ZEBD-7-8 ZEBD-7-9 ZEBD-7-10 ZEBD-7-12 ZEBD-7-15 ZEBD-7-18 ZEBD-8-5 ZEBD-8-7 ZEBD-8-9 ZEBD-8-12 ZEBD-8-15 ZSO-10-2 ZSO-10-3 ZSO-10-4 ZSO-10-5 ZSO-10-6 ZSO-10-7 ZSO-10-8 ZSO-10-9 ZSO-10-10 ZSO-10-12 ZSO-10-15 ZSO-5-3 ZSO-5-4 ZSO-5-5 ZSO-5-7 ZSO-5-9 ZSO-5-10 ZSO-5-12 ZSO-5-15 ZSO-6-4 ZSO-6-7 ZSO-6-9 ZSO-6-10 ZSO-7-3 ZSO-7-4 ZSO-7-5 ZSO-7-6 ZSO-7-7 ZSO-7-9 ZSO-7-10 ZSO-7-12 ZSO-7-15 ZSO-7-16 ZSO-7-18 ZSO-8-4 ZSO-8-5 ZSO-8-7 ZSO-8-9 ZSO-8-10 ZSO-8-12 ZSO-8-15 CLSO-SF-7-5 CLSO-SF-7-7 CLSO-SF-7-9 CLSO-SF-7-12 CLSO-SF-7-15 CLSO-SF-10-5 CLSO-SF-10-7 CLSO-SF-10-9 CLSO-SF-10-12 CLSO-SF-10-15			

Product Service

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH 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 during application review)	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
Not applicable	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-01-26	713212698	Initial issue