DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

optimed Medizinische Instrumente GmbH
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Date 2024-09-26

Subject: Notified Body Confirmation Letter

Our reference: 50066-CoL-02, Rev. 1

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 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Dear Mr. Berner-Smiatek

optimed Medizinische Instrumente GmbH
Ferdinand-Porsche-Straße 11
76275 Ettlingen
Deutschland

SRN Number (if available): DE-MF-000021679

Table 1 identifies the devices for which a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR has been concluded between optimed Medizinische Instrumente GmbH and DEKRA Certification GmbH and for which DEKRA Certification GmbH is also responsible 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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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.

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)

Validity of this confirmation letter:

For products included in table 1 and 2:

Until the end of applicable transition timelines specified in Article 120.3c of MDR (as amended by (EU) 2023/607

This confirmation letter with the registration no. 50066-CoL-01, Rev. 1, is invalid with immediate effect.

On behalf of the Notified Body,

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Karin Leicht

Enclosures:

Confirmation Letter Annex

Table 1

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	Agreement for Conformity Assessment
sinus-SuperFlex-635 Basic UDI-DI: 4047199SINSF63596	Class IIb	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08; NB0124 DEKRA Certification GmbH	50066-CA-00
BigLumen Aspiration Catheter & Set Basic UDI-DI: 4047199BIGLUMEN3M	Class IIa	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08; NB0124 DEKRA Certification GmbH	50066-CA-00
VarioTip Standard / VarioTip Premium Basic UDI-DI: 4047199VARIOTIPEY	Class I devices placed on the market in sterile condition	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08; NB0124 DEKRA Certification GmbH	50066-CA-00
sinus-XL Flex Basic UDI-DI: 4047199SINXLFLEXYW	Class III	N/A	50066-16-08 and Revision 1 of Annex to Certificate 50066-16-08; EC Design Examination Certificate 50066-23-K6 and Revision 0 of Annex to 50066-23-K6 NB0124 DEKRA Certification GmbH	50066-CA-00
Tentos 5F Basic UDI-DI: 4047199TENTOS5FFH	Class IIb	sinus-SuperFlex-535	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08; NB0124 DEKRA Certification GmbH	50066-CA-00

Zelos PTA Dilatation Catheter Basic UDI-DI: 4047199ZELOSV4Z	Class IIa	Zelos PTA-Balloon Catheter	50066-16-08 and Revision 1 of Annex to Certificate 50066-16-08; EC Design Examination Certificate 50066-23-I3 (expired on August 04, 2021)	50066-CA-00
sinus-Repo-Visual 6F Basic UDI-DI: 4047199SINREPOVI6FCV	Class IIb	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08; NB0124 DEKRA Certification GmbH	50066-CA-00
sinus-XL Basic UDI-DI: 4047199SINXL3K	Class III	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08; EC Design Examination Certificate 50066-23-K6 and Revision 0 of Annex to 50066-23-K6 NB0124 DEKRA Certification GmbH	50066-CA-00
sinus-XL 6F Basic UDI-DI: 4047199SINXL6F5W	Class III	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08; EC Design Examination Certificate 50066-23-K6 and Revision 0 of Annex to 50066-23-K6 NB0124 DEKRA Certification GmbH	50066-CA-00
sinus-Venous Basic UDI-DI: 4047199SINVENOUSZ4	Class IIb	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08 NB0124 DEKRA Certification GmbH	50066-CA-00
sinus-Obliquus Basic UDI-DI:	Class IIb	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08	50066-CA-00

4047199SINOBLIQUUSA8			NB0124 DEKRA Certification GmbH	
sinus-SuperFlex-DS Basic UDI-DI: 4047199SINSFDS6N	Class III	N/A	50066-16-08 and Revision 1 of Annex to Certificate 50066-16-08; EC Design Examination Certificate 50066-23-K6 and Revision 0 of Annex to 50066-23-O2 NB0124 DEKRA Certification GmbH	50066-CA-00
Dilators Basic UDI-DI: 4047199DILATUC	Class IIa	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08 NB0124 DEKRA Certification GmbH	50066-CA-00
Splitsheath Basic UDI-DI: 4047199SPLITSH9J	Class IIa	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08 NB0124 DEKRA Certification GmbH	50066-CA-00
Epsylar – Percutaneous Introducer Sheath Basic UDI-DI: 4047199EPYEC	Class IIa	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08 NB0124 DEKRA Certification GmbH	50066-CA-00
Tentos 4F Basic UDI-DI: 4047199TENTOS46Q	Class IIb	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08 NB0124 DEKRA Certification GmbH	50066-CA-00
CO2-Angioset Basic UDI-DI: 4047199CO2ANGIORD	Class IIa	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08 NB0124 DEKRA Certification GmbH	50066-CA-00
Angiography Needles Basic UDI-DI: 4047199ANGNATN	Class IIa	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08	50066-CA-00

			NB0124 DEKRA Certification GmbH	
Initial puncture Needles Basic UDI-DI: 4047199INIPUNK3S	Class IIa	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08 NB0124 DEKRA Certification GmbH	50066-CA-00
Chiba Needles Basic UDI-DI: 4047199CHIBAS8	Class IIa	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08 NB0124 DEKRA Certification GmbH	50066-CA-00
Ureteral Stents and Sets (Double-J) Basic UDI-DI: 4047199UROSTENT2BX6	Class IIb	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08 NB0124 DEKRA Certification GmbH	50066-CA-00
Ureteral Stents and Sets (Mono-J) Basic UDI-DI: 4047199UROSTENT2BSLSX	Class IIb	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08 NB0124 DEKRA Certification GmbH	50066-CA-00
<u>Gastroenterological Drainages:</u> **Biliary Endoprotheses** **Bile Duct Introduction Set** **Pusher** **Pancreatic Stent** Basic UDI-DI: 4047199GSENDOWG 4047199GSIK3H 4047199PUSHER5B	Class IIa	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08 NB0124 DEKRA Certification GmbH	50066-CA-00
Drainage Catheter and Drainage Catheters and Sets Basic UDI-DI: 4047199DRAINAGE2C	Class IIa	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08 NB0124 DEKRA Certification GmbH	50066-CA-00
Drainage Catheter and Drainage	Class IIa	N/A	50066-16-08 and Revision 1 Annex	50066-CA-00

Catheters and Sets – NSAD Basic UDI-DI: 4047199DRAINBSK3Z			to the Certificate 50066-16-08 NB0124 DEKRA Certification GmbH	
Silaro Nephrostomy Balloon Catheter Basic UDI-DI: 4047199DRAINBLN3J	Class IIa	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08 NB0124 DEKRA Certification GmbH	50066-CA-00
Equadus Tipless Nitinol Stone Basket Basic UDI-DI: 4047199SFKEQ	Class IIa	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08 NB0124 DEKRA Certification GmbH	50066-CA-00
Universal Stone Basket Basic UDI-DI: 4047199SFKU4W	Class IIa	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08 NB0124 DEKRA Certification GmbH	50066-CA-00
Accessories Is: **Adapter** Ureteric Catheter **Connector** Tuohy Borst **Adapter** URS Basic UDI-DI: 4047199ADAB4 4047199UCCE9 4047199TBADV	Class I devices placed on the market in sterile condition	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08 NB0124 DEKRA Certification GmbH	50066-CA-00
Hydra "Black" Guide wires Basic UDI-DI: 4047199FDIIYQ	Class IIa	N/A	50066-16-08 and Revision 1 Annex to the Certificate 50066-16-08 NB0124 DEKRA Certification GmbH	50066-CA-00