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TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

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Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
15692	713347895, 713347896, 713347898	medical_devices@tuvsud.com	/	2024-09-25	1 of 8

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 015692 0508 Rev. 00

Reference: 713347895 | 713347896 | 713347898

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: DE-MF-000006357

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.
- 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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 015692 0508 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-09-25

TÜV SÜD Product Service GmbH
Medical and Health Services

Torsten Alt
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Arianit Fazlija
Application Reviewer

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
34342Neutralelektrode3D	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342SillikonballonND	☒ Class IIb implantable (non-exempted)	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342AbsaugkatheterWU	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 015692 0503 Rev. 00 NB# 0123
34342AbsaugsystemG5	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev.01 NB# 0123
34342ASchlauchSQV	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 015692 0504 Rev. 01 NB# 0123
34342BeatmungsbGF	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342BeatmungsH9	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342BezugLampeEZ	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 015692 0504 Rev. 01 NB# 0123
34342CSchuheSG3	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 015692 0504 Rev. 01 NB# 0123
34342DarmrohrXL	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342DrainageUD	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342Einnahmeglas7T	☒ Class I devices with measuring function	☒ N/A	☒ Certification as follows: Certificate # G3M 015692 0506 Rev. 00 NB# 0123
34342ElektrodenreinigerLF	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 015692 0504 Rev. 01 NB# 0123

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
34342EmbolekkVQ	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342Endotrachealtubus34	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342Endotrachfuehrung89	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342FadenMS4V	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 015692 0504 Rev. 01 NB# 0123
34342FadenziehSA3	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 015692 0504 Rev. 01 NB# 0123
34342Filter79	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342FrazierHY	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342GasinsufflationWF	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342GasprobensQA	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342GefaessA8	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342GuedeltubeN4	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 015692 0504 Rev. 01 NB# 0123
34342HautklammergeraetCK	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 015692 0503 Rev. 00 NB# 0123
34342HautstanzeY3	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342InfusionsWX	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123

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
34342IrrigationsSTB	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 015692 0504 Rev. 01 NB# 0123
34342KatheterapliHT	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342KlammerentMM	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 015692 0504 Rev. 01 NB# 0123
34342KuenstlicheNase9P	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342KVerschlussPF	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 015692 0504 Rev. 01 NB# 0123
34342LaryngealmaskeMT	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342LatexballonkHE	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342Nabelk3F	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 015692 0504 Rev. 01 NB# 0123
34342OrthosaugerMG	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342PEEPVentilYB	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342RDrainage7M	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342Redon6P	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342Reservoir2J	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 015692 0504 Rev. 01 NB# 0123
34342SauerstoffkF7	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123

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
34342Sauerstoffver3G	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342SaugAE	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342SBeutel92	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 015692 0504 Rev. 01 NB# 0123
34342SetK9H	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 015692 0504 Rev. 01 NB# 0123
34342SetM9M	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 015692 0504 Rev. 01 NB# 0123
34342SetS9Z	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 015692 0504 Rev. 01 NB# 0123
34342SilikonMaskeMY	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342SkalpelleSL	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342SkalpellklingeMZ	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342SMaskeZQ	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342SondeD9Y	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342SondeMAJ	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342SpuelsFA	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342Stuhldrainage73	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123

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
34342SUltraschallK7	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 015692 0504 Rev. 01 NB# 0123
34342SVerschlussX7	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 015692 0504 Rev. 01 NB# 0123
34342TKatheterD7	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342TrachealsQ8	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342TSBeutelGV	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 015692 0504 Rev. 01 NB# 0123
34342TSystemNY	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 015692 0504 Rev. 01 NB# 0123
34342UBeutelA4	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 015692 0504 Rev. 01 NB# 0123
34342UBeutelMNL	☒ Class I devices in sterile condition ☒ Class I devices with measuring function	☒ N/A	☒ Certification as follows: Certificate #; G2MS 015692 0505 Rev. 00 NB# 0123
34342UrokatheterKD	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342VBezugSAT	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 015692 0504 Rev.01 NB# 0123
34342VerneblerSW8	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123
34342Wendltubus42	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 015692 0502 Rev. 01 NB# 0123

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
34342LaryngoskopC8	☒ Class I reusable surgical instruments	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024/09/25	713347895, 713347896, 713347898	Initial issue