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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
50972	713308380 713310442	+86 10 6455 0022 Dawei.Hu@tuvsud.com		2023-11-15	1 of 8

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 050972 0055 Rev. 01

Reference: 713308380 | 713310442

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: CN-MF-000007715

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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 (3a) 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)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further 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 050972 0055 Rev. 01

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
15.11.2023

TÜV SÜD Product Service GmbH
Medical and Health Services

Hu Dawei
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Michael Mauermeir
Michael Mauermeir (Nov 15, 2023 13:53 GMT+1)

Michael Mauermeir
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
Device 1 **Pulse Oximeter** **Basic UDI-DI:** **69450401CMS50DFG**	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; NB#: 0123
Device 2 **Patient Monitor** **Basic UDI-DI:** **69450401CMS8000E9**	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; NB#: 0123
Device 3 **Electrocardiograph** **Basic UDI-DI:** **69450401ECG1212G5V**	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; NB#: 0123
Device 4 **Electronic Sphygmomanometer** **Basic UDI-DI:** **69450401CONTEC08AAN**	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; NB#: 0123
Device 5 **Electronic Sphygmomanometer** **Basic UDI-DI:** **69450401CONTEC08CAS**	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; 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
	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 6 **Ambulatory Blood Pressure Monitor** **Basic UDI-DI:** **69450401ABPM50D4**	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; NB#: 0123
Device 7 **Mesh Nebulizer** **Basic UDI-DI:** **69450401NE-M01BK**	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; NB#: 0123
Device 8 **Infrared Thermometer** **Basic UDI-DI:** **69450401TP500KY**	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; NB#: 0123
Device 9 **Oxygen Concentrator** **Basic UDI-DI:** **69450401CONTEC21WV**	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; NB#: 0123
Device 10 **Capnograph** **Basic UDI-DI:** **69450401CA10MBY**	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; 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
	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 11 **Fetal Monitor** **Basic UDI-DI:** **69450401CMS800GFM**	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; NB#: 0123
Device 12 **B-Ultrasound Diagnostic System** **Basic UDI-DI:** **69450401CMS600P2HG**	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; NB#: 0123
Device 13 **Spirometer** **Basic UDI-DI:** **69450401SP70BLZ**	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; NB#: 0123
Device 14 **Pocket Fetal Doppler** **Basic UDI-DI:** **69450401CONTEC10CA7**	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; NB#: 0123
Device 15 **Sleep apnea screen meter** **Basic UDI-DI:** **69450401RS01QA**	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; 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
	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 16 **ECG Workstation** **Basic UDI-DI:** **69450401CONTEC8000GA5**	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; NB#: 0123
Device 17 **Portable ECG Monitor** **Basic UDI-DI:** **69450401PM10NX**	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; NB#: 0123
Device 18 **Dynamic ECG Systems** **Basic UDI-DI:** **69450401TLC6000GX**	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; NB#: 0123
Device 19 **Multi-parameter Vital Signs Monitor** **Basic UDI-DI:** **69450401HMS7500HG**	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; NB#: 0123
Device 20 **Digital Brain Electric Activity Mapping** **Basic UDI-DI:** **69450401KT88Q4**	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; 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
	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 21 **Pulse Oximeter Probe** **Basic UDI-DI:** **69450401ESA0008AB**	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; NB#: 0123
Device 22 **EMG/EP System** **Basic UDI-DI:** **69450401CMS6600BGT**	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; NB#: 0123
Device 23 **Infusion Pump** **Basic UDI-DI:** **69450401SP750LE**	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #: G1 050972 0050 Rev.04; 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
Not applicable	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Revision History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
19.09.2023	713308380	Initial issue
15.11.2023	713310442	Addition of Device 23 (Basic UDI-DI: 69450401SP750LE) Addition of confirmation letter validity link Layout update