



**Add value.
Inspire trust.**

TÜV SÜD Product Service GmbH · Germany

Guangdong Transtek Medical Electronics Co., Ltd,
Zone A, No. 105,
Dongli Road, Torch Development District,
528437 Zhongshan, Guangdong,
PEOPLE`S REPUBLIC OF CHINA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
82800	713312454	medical_devices@tuvsud.com	N/A	2024-06-11	1 of 13

**TÜV SÜD Product Service GmbH
Confirmation Letter
CL 082800 0051 Rev. 00**

Reference: 713312454

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-000010684

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.

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Walter Reithmaier (CEO)
Patrick van Welij

TÜV SÜD Product Service GmbH

Germany

tuvsud.com/ps
Hotline:

TUV®



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=CL_082800_0051_Rev.00

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

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

11th June 2024.

TÜV SÜD Product Service GmbH
Medical and Health Services

Handwritten signature of May Yuan in blue ink.

May Yuan
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Handwritten signature of Tunde Junaid in blue ink.

Tunde Junaid
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
Blood Pressure Monitor Basic UDI-DI: 69328253MDR04PW Model: TMB-1598-S, TMB-1117-S	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253TMB1491PE Model: TMB-1491-S TMB-1491-DS	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253LS802GPM3 Model: LS802-GP	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR05PY Model: TMB-1775-ZY	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-1775-A	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had



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
	<input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Blood Pressure Monitor Basic UDI-DI: 69328253TMB1970ZY8Z Model: TMB-1776-ZY	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-1776 TMB-1491-AS TMB-1585-S TMB-995-S	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR04PW Model: TMB-2285-B	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-1598-BS LS810-BS BC 54 TMB-2085 BC 87	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR05PY Model: TMB-2266	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: 2000 H-BP100SBP-CE	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR06Q2 Model: TMB-2296-B	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: LS808-S	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had



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
	<input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	LS808-BS	granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR08Q6 Model: TMB-2287-B	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-1490-BS	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR08Q6 Model: TMB-2287-K	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-1490-S TMB-1490-AS TMB-1490-CS TMB-1873	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253TMB1970ZY8Z Model: TMB-1776-BZY	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-1491-BS TMB-1585-BS TMB-995-BS	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR05PY Model: TMB-2272-ZY	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-1112-S	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had



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	<input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR05PY Model: TMB-2272-AZY	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-1112-AS	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253TMB1970ZY8Z Model: TMB-1970-ZY	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-1597-S TMB-1970	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR04PW Model: TMB-2285	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: LS810-S TMB-988-S TMB-2085-N	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR04PW Model: TMB-1581-ZY	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-1581-S	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had



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	<input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR07Q4 Model: TMB-2273-B	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-1583-BS TMB-1583-S	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR05PY Model: TMB-2276	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-1872	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR05PY Model: TMB-2276-B	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-1872-B	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR05PY Model: TMB-2276-A	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-1872-T	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had



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
	<input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	TMB-1872-A	granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR05PY Model: TMB-2284-T	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-2084-T TMB-2084-KT	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR05PY Model: TMB-2271-A	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-2080-A	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR05PY Model: TMB-2271-K	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-2080-K	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR05PY Model: TMB-2271	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-2080-N	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had



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
	<input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR05PY Model: TMB-2271-B	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-2080	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR05PY Model: TMB-2275-B	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-2083	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR05PY Model: TMB-2275-K	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-2083-K	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR05PY Model: TMB-2275	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-2083-N	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had



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
	<input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR05PY Model: TMB-2284-B	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-2084 TMB-2084-A	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR05PY Model: TMB-2284	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-2084-N	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR07Q4 Model: TMB-2288-B	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-2088	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR07Q4 Model: TMB-2288-BT	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-2088-T	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had



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
	<input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Blood Pressure Monitor Basic UDI-DI: 69328253MDR04PW Model: TMB-2285-K	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: TMB-2085-K	<input type="checkbox"/> Certification as follows: Certificate #G1 082800 0026 Rev. 01 NB# 0123 or <input type="checkbox"/> 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#



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: N/A

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	Not applicable	Not applicable	Not applicable

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-06-11	713312454	Initial issue