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Inspire trust.**

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

Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls NY 13153
USA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
EC-FLC-010-22					
EC-FLC-010-22_DQS	713302660				
EC-FLC-010-22_GMED	ITA2012451_TS	medical_devices@tuvsud.com		2024-09-24	1 of 15

**TÜV SÜD Product Service GmbH
Confirmation Letter
CL 093242 0013 Rev. 01**

Reference: 713302660 | ITA2012451_TS

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: US-MF-000013394

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.

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

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- 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_093242_0013_Rev.01

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH, 2024-09-24

TÜV SÜD Product Service GmbH
Medical and Health Services

SIGN-ID 964713
20/09/2024

Riccardo Cottone

A handwritten signature in blue ink, appearing to read 'R. Cottone'.

Riccardo Cottone

Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

A handwritten signature in blue ink, appearing to read 'M. Bonczar'.

Michael Bonczar

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 Name: SureTemp Plus 690 Thermometer Device Name: SureTemp Plus 692 Thermometer BUDI: 0732094GMN901053F3	<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"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #1 314505 MR2; NB# 0297 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives 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#
Device Name: SureTemp Plus Probe BUDI: 0732094GMN901113EU	<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"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #1 314505 MR2; NB# 0297 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives 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#
Device Name: Braun ThermoScan PRO 9000 BUDI: 0732094GMN901054F5	<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"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input checked="" type="checkbox"/> Certification as follows: Certificate #1 314505 MR2; NB# 0297 or



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 in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device <input type="checkbox"/> Class I reusable surgical instruments	Individual Article number: Braun Thermoscan PRO 6000 Ear Thermometer 06000-200; 06000-300	<input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives 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#
Device Name: ProBP 4000 Digital Blood Pressure Device BUDI: 0732094GMN901198FW	<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"/> Class I reusable surgical instruments	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: Connex ProBP Series Digital Blood Pressure Device 34BXWT-2; 34XFHT-2; 34XFHT-4; 34XFHT-6; 34XFHT-B; 34XFST-2; 34XFST-4; 34XFST-6; 34XFST-B; 34XFWT-2; 34XFWT-4; 34XFWT-6; 34XFWT-B; 34XXHT-2; 34XXHT-4; 34XXHT-6; 34XXHT-B; 34XXST-2; 34XXST-4; 34XXST-6; 34XXST-B; 34XXWT-2; 34XXWT-4; 34XXWT-6; 34XXWT-B;	<input checked="" type="checkbox"/> Certification as follows: Certificate #1 314505 MR2; NB# 0297 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives 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#
Device Name: ELI 280 Electrocardiograph BUDI: 0732094GMN901132EY	<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 checked="" type="checkbox"/> Certification as follows: Certificate #1 35913 rev.3; NB# 0459 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or



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 reusable surgical instruments		<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#
Device Name: ELI 150C Electrocardiograph BUDI: 0732094GMN901129FB	<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"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #1 35913 rev.3; NB# 0459 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives 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#
Device Name: ELI 230 Electrocardiograph BUDI: 0732094GMN901130EU	<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"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #1 35913 rev.3; NB# 0459 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives 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#
Device Name: ELI 380 Electrocardiograph BUDI: 0732094GMN901133F2	<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"/> N/A or	<input checked="" type="checkbox"/> Certification as follows: Certificate #1 35913 rev.3; NB# 0459 or



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 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"/> Class I reusable surgical instruments	<input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives 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#
Device Name: H12PLUS Holter Monitor BUDI: 0732094GMN901141EZ	<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"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #1 35913 rev.3; NB# 0459 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives 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#
Device Name: H3PLUS Holter Monitor BUDI: 0732094GMN901142F3	<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"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #1 35913 rev.3; NB# 0459 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)



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
			Evidence #1; CA#
Device Name: Qstress System Device Name: Xscribe System BUDI: 0732094GMN901144F7	<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"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #1 35913 rev.3; NB# 0459 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives 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#
Device Name: Hscribe BUDI: 0732094GMN901143F5	<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"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #1 35913 rev.3; NB# 0459 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives 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#
Device Name: Welch Allyn Spot Vital Signs 4400 BUDI: 0732094GMN901057FB	<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 checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #1 314505 MR2; NB# 0297 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives



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 <input type="checkbox"/> Class I reusable surgical instruments		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#
Device Name: Welch Allyn Connex Spot Monitor BUDI: 0732094GMN901058FD	<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"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #1 314505 MR2; NB# 0297 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives 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#
Device Name: Welch Allyn "Seymour" Vital Signs Monitor BUDI: 0732094GMN901188FT	<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"/> Class I reusable surgical instruments	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: Connex Vital Signs Monitor (CVSM): 67MCEP-2; 67MCEP-4; 67MCEP-6; 67MCEP-B; 67MCEX-2; 67MCEX-4; 67MCEX-6; 67MCEX-B; 67MCTP-2; 67MCTP-4; 67MCTP-6; 67MCTP-B; 67MCTX-2; 67MCTX-4; 67MCTX-6; 67MCTX-B; 67MCXP-2; 67MCXP-4; 67MCXP-6; 67MCXP-B;	<input checked="" type="checkbox"/> Certification as follows: Certificate #1 314505 MR2; NB# 0297 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives 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#



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
		67MCXX-2; 67MCXX-4; 67MCXX-6; 67MCXX-B; 67MXDX-2; 67MXDX-4; 67MXDX-6; 67MXDX-B; 67MXEP-2; 67MXEP-4; 67MXEP-6; 67MXEP-7; 67MXEP-B; 67MXEX-2; 67MXEX-4; 67MXEX-6; 67MXEX-7; 67MXEX-B; 67MXTP-2; 67MXTP-4; 67MXTP-6; 67MXTP-7; 67MXTP-B; 67MXTX-2; 67MXTX-4; 67MXTX-6; 67MXTX-7; 67MXTX-B; 67MXXP-2; 67MXXP-4; 67MXXP-6; 67MXXP-7; 67MXXP-B; 67MXXX-2; 67MXXX-4; 67MXXX-6; 67MXXX-7; 67MXXX-B; 67NCDX-2; 67NCDX-4; 67NCDX-6; 67NCDX-B; 67NCEP-2; 67NCEP-4; 67NCEP-6; 67NCEP-B; 67NCEX-2; 67NCEX-4; 67NCEX-6; 67NCEX-B; 67NCTP-2; 67NCTP-4; 67NCTP-6; 67NCTP-B; 67NCTX-2; 67NCTX-4; 67NCTX-6; 67NCTX-7 67NCTX-B; 67NCXP-2; 67NCXP-4; 67NCXP-6; 67NCXP-B; 67NCXX-2; 67NCXX-4; 67NCXX-6; 67NCXX-B; 67NXDX-2; 67NXDX-4; 67NXDX-6; 67NXDX-B; 67NXEP-2; 67NXEP-4; 67NXEP-6; 67NXEP-7; 67NXEP-B; 67NXTP-2; 67NXTP-4; 67NXTP-6; 67NXTP-7; 67NXTP-B; 67NXXP-2; 67NXXP-4; 67NXXP-6; 67NXXP-7; 67NXXP-B; 67NXEX-2; 67NXEX-4; 67NXEX-6; 67NXEX-7; 67NXEX-B; 67NXTX-2; 67NXTX-4; 67NXTX-6; 67NXTX-7; 67NXTX-B; 67NXXX-2;	



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
		67NXXX-4; 67NXXX-6; 67NXXX-7; 67NXXX-B; 68MCEP-2; 68MCEP-4; 68MCEP-6; 68MCEP-B; 68MCEX-2; 68MCEX-4; 68MCEX-6; 68MCEX-B; 68MCTP-2; 68MCTP-4; 68MCTP-6; 68MCTP-B; 68MCTX-2; 68MCTX-4; 68MCTX-6; 68MCTX-B; 68MCXP-2; 68MCXP-4; 68MCXP-6; 68MCXP-B; 68MCXX-2; 68MCXX-4; 68MCXX-6; 68MCXX-7; 68MCXX-B; 68MXEP-2; 68MXEP-4; 68MXEP-6; 68MXEP-7; 68MXEP-B; 68MXTP-2; 68MXTP-4; 68MXTP-6; 68MXTP-7; 68MXTP-B; 68MXXP-2; 68MXXP-4; 68MXXP-6; 68MXXP-7; 68MXXP-B; 68MXDX-2; 68MXDX-4; 68MXDX-6; 68MXDX-B; 68MXEX-2; 68MXEX-4; 68MXEX-6; 68MXEX-7; 68MXEX-B; 68MXTX-2; 68MXTX-4; 68MXTX-6; 68MXTX-7; 68MXTX-B; 68MXXX-2; 68MXXX-4; 68MXXX-6; 68MXXX-7; 68MXXX-B; 68NCDX-2; 68NCDX-4; 68NCDX-6; 68NCDX-B; 68NCEP-2; 68NCEP-4; 68NCEP-6; 68NCEP-B; 68NCEX-2; 68NCEX-4; 68NCEX-6; 68NCEX-B; 68NCTP-2; 68NCTP-4; 68NCTP-6; 68NCTP-B; 68NCTX-2; 68NCTX-4; 68NCTX-6; 68NCTX-B; 68NCXP-2; 68NCXP-4; 68NCXP-6; 68NCXP-B; 68NCXX-2; 68NCXX-4; 68NCXX-6; 68NCXX-B; 68NXEP-2; 68NXEP-4; 68NXEP-6;	



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
		<p>68NXEP-7; 68NXEP-B; 68NXTP-2; 68NXTP-4; 68NXTP-6; 68NXTP-7; 68NXTP-B; 68NXXP-2; 68NXXP-4; 68NXXP-6; 68NXXP-7; 68NXXP-B; 68NXDX-2; 68NXDX-4; 68NXDX-6; 68NXDX-B; 68NXEX-2; 68NXEX-4; 68NXEX-6; 68NXEX-7; 68NXEX-B; 68NXTX-2; 68NXTX-4; 68NXTX-6; 68NXTX-7; 68NXTX-B; 68NXXX-2; 68NXXX-4; 68NXXX-6; 68NXXX-7; 68NXXX-B. Connex Integrated Wall System (CIWS): 84MTVE2-2; 84MTVE2-4; 84MTVE2-6; 84MTVE2-B; 84MTVEC-2; 84MTVEC-4; 84MTVEC-6; 84MTVEC-7; 84MTVEC-B; 84MTVEP-2; 84MTVEP-4; 84MTVEP-6; 84MTVEP-7; 84MTVEP-B; 84MTVEX-2; 84MTVEX-4; 84MTVEX-6; 84MTVEX-7; 84MTVEX-B; 84MTVX2-2; 84MTVX2-4; 84MTVX2-6; 84MTVX2-B; 84MTVXC-2; 84MTVXC-4; 84MTVXC-6; 84MTVXC-7; 84MTVXC-B; 84MTVXP-2; 84MTVXP-4; 84MTVXP-6; 84MTVXP-7; 84MTVXP-B; 84MTVXX-2; 84MTVXX-4; 84MTVXX-6; 84MTVXX-7; 84MTVXX-B; 84MXVEC-2; 84MXVEC-4; 84MXVEC-6; 84MXVEC-7; 84MXVEC-B; 84MXVEP-2; 84MXVEP-4; 84MXVEP-6; 84MXVEP-7; 84MXVEP-B; 84MXVEX-2; 84MXVEX-4; 84MXVEX-6; 84MXVEX-7; 84MXVEX-B; 84MXVXC-2; 84MXVXC-4; 84MXVXC-6; 84MXVXC-7; 84MXVXC-B; 84MXVXP-2; 84MXVXP-4;</p>	



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
		84MXVXP-6; 84MXVXP-7; 84MXVXP-B; 84MXVXX-2; 84MXVXX-4; 84MXVXX-6; 84MXVXX-7; 84MXVXX-B; 84NTVE2-2; 84NTVE2-4; 84NTVE2-6; 84NTVE2-B; 84NTVEC-2; 84NTVEC-4; 84NTVEC-6; 84NTVEC-7; 84NTVEC-B; 84NTVEP-2; 84NTVEP-4; 84NTVEP-6; 84NTVEP-7; 84NTVEP-B; 84NTVEX-2; 84NTVEX-4; 84NTVEX-6; 84NTVEX-7; 84NTVEX-B; 84NTVX2-2; 84NTVX2-4; 84NTVX2-6; 84NTVX2-B; 84NTVXC-2; 84NTVXC-4; 84NTVXC-6; 84NTVXC-7; 84NTVXC-B; 84NTVXP-2; 84NTVXP-4; 84NTVXP-6; 84NTVXP-7; 84NTVXP-B; 84NTVXX-2; 84NTVXX-4; 84NTVXX-6; 84NTVXX-7; 84NTVXX-B; 84NXVEC-2; 84NXVEC-4; 84NXVEC-6; 84NXVEC-7; 84NXVEC-B; 84NXVEP-2; 84NXVEP-4; 84NXVEP-6; 84NXVEP-7; 84NXVEP-B; 84NXVEX-2; 84NXVEX-4; 84NXVEX-6; 84NXVEX-7; 84NXVEX-B; 84NXVXC-2; 84NXVXC-4; 84NXVXC-6; 84NXVXC-7; 84NXVXC-B; 84NXVXP-2; 84NXVXP-4; 84NXVXP-6; 84NXVXP-7; 84NXVXP-B; 84NXVXX-2; 84NXVXX-4; 84NXVXX-6; 84NXVXX-7; 84NXVXX-B; 84XTVEC-2; 84XTVEC-4; 84XTVEC-6; 84XTVEC-7; 84XTVEC-B; 84XTVEP-2; 84XTVEP-4; 84XTVEP-6; 84XTVEP-7; 84XTVEP-B; 84XTVEX-2; 84XTVEX-4; 84XTVEX-6; 84XTVEX-7; 84XTVEX-B; 84XTVXC-2; 84XTVXC-4; 84XTVXC-6;	



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
		84XTVXC-7; 84XTVXC-B; 84XTVXP-2; 84XTVXP-4; 84XTVXP-6; 84XTVXP-7; 84XTVXP-B; 84XTVXX-2; 84XTVXX-4; 84XTVXX-6; 84XTVXX-7; 84XTVXX-B; 84XXVEC-2; 84XXVEC-4; 84XXVEC-6; 84XXVEC-7; 84XXVEC-B; 84XXVEP-2; 84XXVEP-4; 84XXVEP-6; 84XXVEP-7; 84XXVEP-B; 84XXVEX-2; 84XXVEX-4; 84XXVEX-6; 84XXVEX-7; 84XXVEX-B; 84XXVXC-2; 84XXVXC-4; 84XXVXC-6; 84XXVXC-7; 84XXVXC-B; 84XXVXP-2; 84XXVXP-4; 84XXVXP-6; 84XXVXP-7; 84XXVXP-B; 84XXVXX-2; 84XXVXX-4; 84XXVXX-6; 84XXVXX-7; 84XXVXX-B; 85MTVE3-2; 85MTVE3-4; 85MTVE3-6; 85MTVE3-7; 85MTVE3-B; 85MTVEC-2; 85MTVEC-4; 85MTVEC-6; 85MTVEC-7; 85MTVEC-B; 85MTVEP-2; 85MTVEP-4; 85MTVEP-6; 85MTVEP-7; 85MTVEP-B; 85MTVEX-2; 85MTVEX-4; 85MTVEX-6; 85MTVEX-7; 85MTVEX-B; 85MTVX3-2; 85MTVX3-4; 85MTVX3-6; 85MTVX3-B; 85MTVXC-2; 85MTVXC-4; 85MTVXC-6; 85MTVXC-7; 85MTVXC-B; 85MTVXP-2; 85MTVXP-4; 85MTVXP-6; 85MTVXP-7; 85MTVXP-B; 85MTVXX-2; 85MTVXX-4; 85MTVXX-6; 85MTVXX-7; 85MTVXX-B; 85MXVEC-2; 85MXVEC-4; 85MXVEC-6; 85MXVEC-7; 85MXVEC-B; 85MXVEP-2; 85MXVEP-4; 85MXVEP-6; 85MXVEP-7; 85MXVEP-B; 85MXVEX-2; 85MXVEX-4; 85MXVEX-6;	



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
		85MXVEX-7; 85MXVEX-B; 85MXVXC-2; 85MXVXC-4; 85MXVXC-6; 85MXVXC-7; 85MXVXC-B; 85MXVXP-2; 85MXVXP-4; 85MXVXP-6; 85MXVXP-7; 85MXVXP-B; 85MXVXX-2; 85MXVXX-4; 85MXVXX-6; 85MXVXX-7; 85MXVXX-B; 85NTVE3-2; 85NTVE3-4; 85NTVE3-6; 85NTVE3-B; 85NTVEC-2; 85NTVEC-4; 85NTVEC-6; 85NTVEC-7; 85NTVEC-B; 85NTVEP-2; 85NTVEP-4; 85NTVEP-6; 85NTVEP-7; 85NTVEP-B; 85NTVEX-2; 85NTVEX-4; 85NTVEX-6; 85NTVEX-7; 85NTVEX-B; 85NTVX3-2; 85NTVX3-4; 85NTVX3-6; 85NTVX3-7; 85NTVX3-B; 85NTVXC-2; 85NTVXC-4; 85NTVXC-6; 85NTVXC-7; 85NTVXC-B; 85NTVXP-2; 85NTVXP-4; 85NTVXP-6; 85NTVXP-7; 85NTVXP-B; 85NTVXX-2; 85NTVXX-4; 85NTVXX-6; 85NTVXX-7; 85NTVXX-B; 85NXVEC-2; 85NXVEC-4; 85NXVEC-6; 85NXVEC-7; 85NXVEC-B; 85NXVEP-2; 85NXVEP-4; 85NXVEP-6; 85NXVEP-7; 85NXVEP-B; 85NXVEX-2; 85NXVEX-4; 85NXVEX-6; 85NXVEX-7; 85NXVEX-B; 85NXVXC-2; 85NXVXC-4; 85NXVXC-6; 85NXVXC-7; 85NXVXC-B; 85NXVXP-2; 85NXVXP-4; 85NXVXP-6; 85NXVXP-7; 85NXVXP-B; 85NXVXX-2; 85NXVXX-4; 85NXVXX-6; 85NXVXX-7; 85NXVXX-B.	



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			



Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024/04/10	713302660	Initial issue
2024/09/24	ITA2012451_TS	Moved products covered by the CL from Table 1 to Table 2