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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
CBW 75302	713301435 713279052 713267483 713301268 713317836 713329280 Franziska Meindl	+49 89 50084-986 Franziska.Meindl@tuvsud.com	-	2024-02-29	1 of 6

**TÜV SÜD Product Service GmbH
Confirmation Letter**

CL 075302 0066 Rev. 00

Reference: 713301435 | 713279052 | 713267483 | 713301268 | 713317836 | 713329280

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-000003322

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

TÜV SÜD Product Service GmbH
Certification Body for Medical Devices
Ridlerstr. 65
80339 Munich
Germany

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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_075302_0066_Rev._00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-02-29

TÜV SÜD Product Service GmbH
Medical and Health Services


[Franziska Meindl \(29/feb/2024 16:17 GMT+1\)](#)

Franziska Meindl
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services



Franziska Eckert
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 Neoprobe® Console, GDS control unit NPCU4 Device Basic UDI-DI: 08419111AD03A000003322QM	<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 #G1 075302 0058 Rev. 00; 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#
Device 2 Neoprobe® Bluetooth wireless probes NPB14S, NPB14A, NPB11L, NPB09S Device Basic UDI-DI: 08419111AD03C000003322SF	<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 #G1 075302 0058 Rev. 00; 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#
Device 3 Neoprobe® 14mm wired probe NPR14 Device Basic UDI-DI: 08419111AD03I000003322XV	<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 #G1 075302 0058 Rev. 00; 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#
Device 4 Neoprobe® External collimator NPE14 Device Basic UDI-DI: 08419111AD03D000003322TC	<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 checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input checked="" type="checkbox"/> Certification as follows: Certificate #G1 075302 0058 Rev. 00; NB# 0123 or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during applica- tion review)	If the MDR device is a sub- stitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Ref- erence(s) of the devices un- der MDR application, and the NB Identification
	<input type="checkbox"/> Class I devices in ster- ile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	Individual Article number:	<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 5 Mammotome Prima™ MR Control Module MRCM1 Device Basic UDI-DI: 08419111AD10A000003322NV	<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 ster- ile 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 corre- sponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #G1 075302 0058 Rev. 00; 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#
Device 6 Mammotome Prima™ MR Footswitch MRFOOT1 Device Basic UDI-DI: 08419111AD10B000003322PS	<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 ster- ile 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 corre- sponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #G1 075302 0058 Rev. 00; 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#
Device 7 Mammotome Prima™ MR Probe MRPROBE08 Device Basic UDI-DI: 08419111AD10C000003322QP	<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 ster- ile 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 corre- sponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #G1 075302 0058 Rev. 00; 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#
Device 8 Mammotome Prima™ MR Tar- geting Set MRTARGET08	<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 #G1 075302 0058 Rev. 00; NB# 0123 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
Device Basic UDI-DI: 08419111AD10D000003322RL	<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"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<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 9 MammoMARK® / CorMARK® Biopsy Site Identifier MAM3001, MAM3002, MAM3008, MRM4002, MRM4008, MAM3014, MMK0801, MMK0802, MMK1001, MMK1002 Device Basic UDI-DI: 08419111IAO04000003322	<input checked="" type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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 #G1 075302 0058 Rev. 00; NB# 0123 Certificate #G7AO 075302 0048 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#
Device 10 HydroMARK™ Biopsy Site Marker 4010-01-08-T1, 4010-01-08-T3, 4010-01-08-T4, 4010-01-08-S1, 4010-03-09-T1, 4010-03-09-T3, 4010-04-09-T1, 4010-04-09-T3, 4010-04-09-T4, 4010-04-09-S3, 4010-01-11-T1, 4010-01-11-T3, 4010-01-11-T4, 4010-02-15-S1, 4010-02-15-S3, 4010-02-15-T1, 4010-02-15-T3, 4010-02-15-T4, 4010-02-15-T5, 4010-03-15-T1-SHORT, 4010-03-15-T3-SHORT, 4010-02-18-T3, 4010-05-08-T1, 4010-05-08-T3, 4010-05-08-T4, 4010-05-10-T1, 4010-05-10-T3, 4010-05-10-T4 Device Basic UDI-DI: 08419111I0005000003322	<input checked="" type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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 #G1 075302 0058 Rev. 00; NB# 0123 Certificate #G7 075302 0056 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:

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	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-02-29	713301435 713279052 713267483 713301268 713317836 713329280	Initial issue