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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 |
|---|---|---|---|---|---|
| 30178 | 200130026555 | medical_devices@tuvsud.com | N/A | 2024-09-23 | 1 of 4 |

**TÜV SÜD Product Service GmbH**
**Confirmation Letter**
**CL 030178 0017 Rev. 00**

**Reference:** 200130026555

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.**

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: DE-MF-000033347

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 030178 0017 Rev. 00

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

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

23rd September 2024.

TÜV SÜD Product Service GmbH
Medical and Health Services

Max Huhn (23. September 2024 14:04 GMT+2)

Max Huhn
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

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 |
|---|---|---|---|
| **RECOMED 0426244947900UW** | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☒ Class IIb / Class IIb implantable (exempted)<br>☐ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☐ N/A<br><br>or<br><br>☒ Identification of the corresponding device under MDD/AIMDD<br>Individual Article number:<br>900.072 | ☒ Certification as follows:<br>G1 030178 0016 Rev. 00 NB 0123<br>or<br><br>☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)<br>Evidence #1; CA#<br>Evidence #2; CA# |
| **URO-2050 0426244947420UB** | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☐ Class IIb / Class IIb implantable (exempted)<br>☒ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☐ N/A<br><br>or<br><br>☒ Identification of the corresponding device under MDD/AIMDD<br>Individual Article number:<br>420.010 | ☒ Certification as follows:<br>G1 030178 0016 Rev. 00 NB 0123<br>or<br>☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)<br>Evidence #1; CA#<br>Evidence #2; CA# |
| **Rundfeldstrahler 0426244947000TH** | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☐ Class IIb / Class IIb implantable (exempted)<br>☒ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A<br><br>or<br><br>☒ Identification of the corresponding device under MDD/AIMDD<br>Individual Article number:<br>900.072 | ☒ Certification as follows:<br>G1 030178 0016 Rev. 00 NB 0123<br>or<br><br>☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)<br>Evidence #1; CA#<br>Evidence #2; CA# |
| **Kleinfeldstrahler (HNO) 0426244947001TK** | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☐ Class IIb / Class IIb implantable (exempted)<br>☒ Class IIa<br>☐ Class I devices in sterile condition | ☒ N/A<br><br>or<br><br>☒ Identification of the corresponding device under MDD/AIMDD<br>Individual Article number:<br>900.072 | ☒ Certification as follows:<br>G1 030178 0016 Rev. 00 NB 0123<br>or<br><br>☐ 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 |
|---|---|---|---|
| | ☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | | Evidence #1; CA#<br>Evidence #2; CA# |
| **Muldenstrahler 0426244947901UY** | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☐ Class IIb / Class IIb implantable (exempted)<br>☒ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A<br><br>or<br><br>☒ Identification of the corresponding device under MDD/AIMDD<br>Individual Article number:<br>900.072 | ☒ Certification as follows:<br>G1 030178 0016 Rev. 00 NB 0123<br>or<br><br>☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)<br>Evidence #1; CA#<br>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 |
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## Confirmation Letter Version History

| Date | TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter | Action |
|---|---|---|
| 2024/09/23 | 200130026555 | Initial issue |