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Inspire trust.**

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

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88454 Hochdorf  
GERMANY

Your reference/letter of	Our reference/name	E-mail	Tel. extension	Date	Page
017939	713335435	medical_devices@tuvsud.com	---	2024-06-27	1 of 6

## **TÜV SÜD Product Service GmbH Confirmation Letter**

**CL 017939 0104 Rev. 00**

**Reference: 713335435**

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-000005058**

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**  
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**Supervisory Board:**  
Holger Lindner (Chairman)  
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**TÜV SÜD Product Service GmbH**  
Application Review  
Ridlerstr. 65  
80339 Munich  
Germany

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see: [www.tuvsud.com/ps-cert?q=cert:CL\\_017939\\_0104\\_Rev.\\_00](http://www.tuvsud.com/ps-cert?q=cert:CL_017939_0104_Rev._00)

In case of inquiries please contact: [medical\\_devices@tuvsud.com](mailto:medical_devices@tuvsud.com)

On behalf of the Notified Body TÜV SÜD Product Service GmbH,  
2024-06-27

TÜV SÜD Product Service GmbH  
Medical and Health Services

TÜV SÜD Product Service GmbH  
Medical and Health Services

A handwritten signature in black ink, appearing to read 'M. Krafczyk', written over a horizontal line.

Martin Krafczyk  
Conformity Assessment Responsible (CARE)

A handwritten signature in blue ink, appearing to read 'K. Fackler', written over a horizontal line.

Konrad Fackler  
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
<p><b>OmniCycle Connect</b></p> <p><b>Basic UDI-DI:</b> 4041925tigoFN</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input type="checkbox"/> N/A</p> <p>or</p> <p><input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD</p> <p>Individual Article number: A000-533</p> <p>Device name under MDD: OmniCycle</p>	<p><input checked="" type="checkbox"/> Certification as follows:</p> <p>Certificate registration no.: 064866 MR2</p> <p>Certificate unique ID: 170770080</p> <p>NB# 0297</p> <p><b>NOTE:</b> TÜV Süd takes over responsibility for appropriate surveillance on <b>2024-06-28</b>.</p>
<p><b>THERA-Trainer tigo</b></p> <p><b>Basic UDI-DI:</b> 4041925tigoFN</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD</p> <p>Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows:</p> <p>Certificate registration no.: 064866 MR2</p> <p>Certificate unique ID: 170770080</p> <p>NB# 0297</p> <p><b>NOTE:</b> TÜV Süd takes over responsibility for appropriate surveillance on <b>2024-06-28</b>.</p>
<p><b>THERA-Trainer veho</b></p> <p><b>Basic UDI-DI:</b> 4041925tigoFN</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD</p> <p>Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows:</p> <p>Certificate registration no.: 064866 MR2</p> <p>Certificate unique ID: 170770080</p> <p>NB# 0297</p> <p><b>NOTE:</b> TÜV Süd takes over responsibility for appropriate surveillance on <b>2024-06-28</b>.</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
<b>THERA-vital</b>  <b>Basic UDI-DI:</b> 4041925tigoFN	<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 registration no.: 064866 MR2 Certificate unique ID: 170770080 NB# 0297  <b>NOTE:</b> TÜV Süd takes over responsibility for appropriate surveillance on <b>2024-06-28</b> .
<b>THERA-live</b>  <b>Basic UDI-DI:</b> 4041925tigoFN	<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 registration no.: 064866 MR2 Certificate unique ID: 170770080 NB# 0297  <b>NOTE:</b> TÜV Süd takes over responsibility for appropriate surveillance on <b>2024-06-28</b> .
<b>THERA-Trainer mobi</b>  <b>Basic UDI-DI:</b> 4041925mobiE8	<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 registration no.: 064866 MR2 Certificate unique ID: 170770080 NB# 0297  <b>NOTE:</b> TÜV Süd takes over responsibility for appropriate surveillance on <b>2024-06-28</b> .



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><b>THERA-Trainer Iyra</b></p> <p><b>Basic UDI-DI:</b> 4041925IyraGK</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD</p> <p>Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows:</p> <p>Certificate registration no.: 064866 MR2</p> <p>Certificate unique ID: 170770080</p> <p>NB# 0297</p> <p><b>NOTE:</b> TÜV Süd takes over responsibility for appropriate surveillance on <b>2024-06-28</b>.</p>
<p><b>THERA-Trainer bemo</b></p> <p><b>Basic UDI-DI:</b> 4041925bemoBN</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input checked="" type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD</p> <p>Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows:</p> <p>Certificate registration no.: 064866 MR2</p> <p>Certificate unique ID: 170770080</p> <p>NB# 0297</p> <p><b>NOTE:</b> TÜV Süd takes over responsibility for appropriate surveillance on <b>2024-06-28</b>.</p>



**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
2024-06-27	713335435	Initial issue