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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
004384	713344218	medical_devices@tuvsud.com		2024-08-21	1 of 5

**TÜV SÜD Product Service GmbH
Confirmation Letter
CL 004384 0006 Rev. 01**

Reference: 713344218

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: MY-MF-000036883

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

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Trade Register Munich HRB 85 742
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(Germany) at tuvsud.com/imprint

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

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(MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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_004384_0006_Rev_01

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-08-21

TÜV SÜD Product Service GmbH
Medical and Health Services

TÜV SÜD Product Service GmbH
Medical and Health Services


[Nur Farrahin Md Zulkifli Farid \(Aug 21, 2024 15:59 GMT+8\)](#)

Nur Farrahin binti Md Zulkifli Farid
Conformity Assessment Responsible (CARE)


[Florian Grentzebach \(Aug 21, 2024 10:21 GMT+2\)](#)

Florian Grentzebach
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>Basic UDI-DI: 05051400LFC042WN2X9V 05051400LFC042WP1XA4 05051400LFC042WT3XAW 05051400LFC043WN2XA8</p> <p>Device name: Sterile Latex Foley Catheter</p>	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #G1 004384 0003 Rev. 01; NB# 0123
<p>Basic UDI-DI: 05051400SFC042WN2XG8 05051400SFC042WP1XGF 05051400SFC042WT3XH9 05051400SFC043WN2XGK</p> <p>Device name: Sterile 100% Silicone Foley Catheter</p>	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #G1 004384 0003 Rev. 01; NB# 0123
<p>Basic UDI-DI: 05051400PFS03GLYXXXU 05051400PFS03STWXX5H</p> <p>Device name: Sterile Prefilled Syringe</p>	<input checked="" type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #G2S 004384 0002 Rev. 03
<p>Basic UDI-DI: 05051400PUB03C1PXXQ3</p> <p>Device name: C1 Paediatric Urine Collector</p>	<input checked="" type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #G2S 004384 0002 Rev. 03
<p>Basic UDI-DI: 05051400SSP03XXXXXJJ</p> <p>Device name: Sterile Catheter Spigot</p>	<input checked="" type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #G2S 004384 0002 Rev. 03
<p>Basic UDI-DI: 05051400SUB03C2XXaUH 05051400SUB03C2XXbUK</p>	<input checked="" type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #G2S 004384 0002 Rev. 03



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
<u>Device name:</u> C2 Sterile Standard Bag			
<u>Basic UDI-DI:</u> 05051400SUB03C4XXcV3 05051400SUB03C4XXeV7 05051400SUB03C4XXfV9 <u>Device name:</u> C4 Sterile Closed System Bag	<input checked="" type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #G2S 004384 0002 Rev. 03
<u>Basic UDI-DI:</u> 05051400SUB03C6XXgVR 05051400SUB03C6XXhVT <u>Device name:</u> C6 Sterile Closed System Bag	<input checked="" type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #G2S 004384 0002 Rev. 03
<u>Basic UDI-DI:</u> 05051400SUB03C7XXcVQ 05051400SUB03C7XXdVS <u>Device name:</u> C7 Sterile Fluid Drainage Bag	<input checked="" type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #G2S 004384 0002 Rev. 03
<u>Basic UDI-DI:</u> 05051400SUB03C8XXgW7 05051400SUB03C8XXhW9 <u>Device name:</u> C8 Sterile Closed System (TUR) Bag	<input checked="" type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #G2S 004384 0002 Rev. 03



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
2024-05-16	MAL-5909190	Initial issue
2024-08-21	MAL-5909190 713344218	Revised template and added Medical Device Name