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

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**TÜV SÜD Product Service GmbH
Confirmation Letter
CL 125821 0001 Rev. 00**

Reference: 713343072

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: IN-MF-000025371

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

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
Zertifizierstelle für Medizinprodukte /
Certification Body for Medical Products
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(MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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_125821_0001_Rev_00

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

This version of the confirmation letter is valid until 2024-09-26.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-08-07

TÜV SÜD Product Service GmbH
Medical and Health Services

A handwritten signature in blue ink, appearing to read 'Vikrant Chowgule'.

Vikrant Chowgule
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

A handwritten signature in blue ink, appearing to read 'Matthias Mumme'.

[Matthias Mumme \(7. August 2024 13:20 GMT+2\)](#)

Matthias Mumme
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
Not applicable	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A

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
I.V Cannula With/without wings & with /without injection valve with/without safety. Without wings & without injection valve Pen 14G,16G,17G,18G, 20G,22G,24G,26G	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #1 10000322575-PA-NA-IND NB# 2460
Infusion Set With/without flow regulator With/without microdrip Vented/non vented infusion set with latex bulb luer slip with 21G Needle Vented/non vented infusion set with Y Site luer lock with Needle 21G	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #1 10000322575-PA-NA-IND NB# 2460
Measure Volume Set With/without flow regulator With Y Site with luer lock Needle 21G 100ML,110ML,150ML	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #1 10000322575-PA-NA-IND NB# 2460
Blood Transfusion Set Single/double chamber with/without airway Vented/non vented blood transfusion Set with latex bulb luer slip with 18G Needle Vented/non vented blood transfusion set with Y Site Luer lock with Needle 18G	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #1 10000322575-PA-NA-IND NB# 2460
Extension tubing High pressure extension line with/without flow regulator 10cm,25cm,50cm,100cm,150cm,200cm,250cm,300cm	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #1 10000322575-PA-NA-IND NB# 2460
Three way stop cock with/without extension tubing	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #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
Non Lipid / Lipid Resistance			10000322575-PA-NA-IND NB# 2460

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-08-07	713343072	Initial issue