



TÜV SÜD Product Service GmbH · Ridlerstr. 65 · 80339 München · Deutschland

**Mehr Wert.
Mehr Vertrauen.**

KD Medical GmbH
Hospital Products
Charlottenstrasse 65
10117 Berlin

Your reference	Our reference/name	Tel./E-Mail	Fax-extension	Date	page
713334568	PS-MHS-TD4/ Leslie Schmidt	+49 89 50084-723 Leslie.Schmidt@tuvsud.com		11. April 2024	1 of 2

TÜV SÜD Product Service GmbH Receipt of formal application

Reference: Order Number 713334568

To whom it may concern,

Confirmation of the status of a formal application 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 with the above stated manufacturer with the following SRN Number:

SRN Number: DE-MF-000006773

The devices covered by the formal application mentioned above are identified in the Table below.

**Please note that this letter only confirms the status of the formal application.
To benefit from the additional transitional provisions in the framework of Regulation EU 2023/607, TÜV SÜD Product Service GmbH and the manufacturer need to sign a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR latest until 26 September 2024.**

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH, 2024-04-11

TÜV SÜD Product Service GmbH
Medical and Health Services

SIGN-ID 903735

Leslie Schmidt (PS-MHS-TD4)
Conformity Assessment Responsible (CARE)

Sitz: München
Handelsregister München HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
USt-IdNr. DE129484267
Informationen gemäß § 2 Abs. 1 DL-InfoV

Aufsichtsrat :
Holger Lindner (Vorsitzender)
Geschäftsführung:
Walter Reithmaier (Sprecher)
Patrick van Welij

TÜV SÜD Product Service GmbH
tuvsud.com/ps
Hotline:

Deutschland





Devices covered by the formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR

Device name or Basic UDI-DI (under MDR application)
KD-Fine
Basic UDI-DI: 4031881B65III8M

Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-04-11	713334568	Initial issue