TÜVNORD

TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany

RONTIS CORPORATION S.A.
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SWITZERLAND

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Reference	Contact	Direct Dial	Date
No: 24.124046/800011/KO	E-Mail: keconomidi@tuv-nord.com	Tel.: +30 2314443610	14 November 2024

Notified Body Confirmation Letter
Reference: P11F014e / 24.04.2024

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 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **TUV NORD CERT GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0044 on NANDO, has 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 following manufacturer:

RONTIS CORPORATION S.A.
7, Bahnhofstrasse
CH6300 Zug
SWITZERLAND
SRN Number: **CH-MF-000031411**

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 the NB 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 the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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, by the 20 Mar 2023 for the relevant devices.

The transition timelines 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 (as amended by (EU) 2023/607), 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 excluding Well-established technologies (WET - 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 or have a 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)

On behalf of the Notified Body,

TÜVNORD i. V.
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i. V. Caroline Schmidt
Deputy Head of Project Management
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

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i. V. Dr. Benjamin Hoy
Head of TIC Management
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

Table 1: Devices covered by this letter and for which the NB 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 at the pre-application stage)	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
Device 1: Nasalou ® Nasal Aspirator Kit	Class I s	N/A	Certificate No. TNP/MDD/0389/5184/2021, TUV NORD POLSKA 2274
Device 2: Nasalou ® Nasal Aspirator Refills (x12, x24	Class I s	N/A	Certificate No. TNP/MDD/0389/5184/2021, TUV NORD POLSKA 2274
Device 3: (RG_)(A)1xxxxxxx Bloodlines for haemodialysis machine universal	Class I s	N/A	Certificate No. TNP/MDD/0388/5184/2021, TUV NORD POLSKA 2274
Device 4: (RG_)2xxxxxxx Bloodlines for Fresenius haemodialysis machine	Class IIa	N/A	Certificate No. TNP/MDD/0388/5184/2021, TUV NORD POLSKA 2274
Device 5: (RG_)(A)3xxxxxxx Bloodlines for Gambro haemodialysis machine	Class IIa	N/A	Certificate No. TNP/MDD/0388/5184/2021, TUV NORD POLSKA 2274
Device 6: (RG_)4xxxxxxx Bloodlines for Hospal/Integra haemodialysis machine	Class IIa	N/A	Certificate No. TNP/MDD/00388/5184/2021, TUV NORD POLSKA 2274
Device 7: (RG_)(A)5xxxxxxx Bloodlines for Nipro haemodialysis machine	Class IIa	N/A	Certificate No. TNP/MDD/0388/5184/2021, TUV NORD POLSKA 2274
Device 8: (RG_)(A)6xxxxxxx Bloodlines for B.Braun haemodialysis machine	Class IIa	N/A	Certificate No. TNP/MDD/0388/5184/2021, TUV NORD POLSKA 2274
Device 9: (RG_)(A)7xxxxxxx Bloodlines for Nikkiso haemodialysis machine	Class IIa	N/A	Certificate No. TNP/MDD/0388/5184/2021, TUV NORD POLSKA 2274
Device10: (RG_)8xxxxxxx Bloodlines for Belco haemodialysis machine	Class IIa	N/A	Certificate No. TNP/MDD/0388/5184/2021, TUV NORD POLSKA 2274
Device 11: (RG_)9xxxxxxx Bloodlines for Baxter haemodialysis machine	Class IIa	N/A	Certificate No. TNP/MDD/0388/5184/2021, TUV NORD POLSKA 2274
Device 12: LRxxxxx Simple Extension Lines	Class IIa	N/A	Certificate No. TNP/MDD/0388/5184/2021, TUV NORD POLSKA 2274
Device 13: LRCxxxxx Simple Extension Lines with Clamp	Class IIa	N/A	Certificate No. TNP/MDD/0388/5184/2021, TUV NORD POLSKA 2274
Device 14: LRRCxxxxx Simple Extension Lines with Roller	Class IIa	N/A	Certificate No. TNP/MDD/0388/5184/2021, TUV NORD POLSKA 2274

Device 15: YRxxxxx SN-Y line adaptor	Class IIa	N/A	Certificate No. TNP/MDD/0388/5184/2021, TUV NORD POLSKA 2274
Device 16: VTxxxxx Micro-Drip Flow Regulator Lines	Class IIa	N/A	Certificate No. TNP/MDD/0388/5184/2021, TUV NORD POLSKA 2274
Device 17: VTxxxxx /DS Micro-Drip Flow Regulator Lines Double Scale	Class IIa	N/A	Certificate No. TNP/MDD/0388/5184/2021, TUV NORD POLSKA 2274
Device 18: SLxxxxx HDF Substitution Lines	Class IIa	N/A	Certificate No. TNP/MDD/0388/5184/2021, TUV NORD POLSKA 2274
Device 19 RGxxxxxxxD DiaStream	Class IIa	N/A	Certificate No. TNP/MDD/0388/5184/2021, TUV NORD POLSKA 2274
Device 20 RGxxxxxxxDS DiaStream Advanced	Class IIa	N/A	Certificate No. TNP/MDD/0388/5184/2021, TUV NORD POLSKA 2274
Device 21 RGxxxxxxxDSR Diastream	Class IIa	N/A	Certificate No. TNP/MDD/0388/5184/2021, TUV NORD POLSKA 2274
Device 22 Cronus Family Peripheral Balloon Catheter – OTW (076300333CF_PBLCATHMK)	Class IIa	/	Certificate No. 1434-MDD-150/2020, PCBC 1434
Device 23 Triton Family Peripheral Balloon Catheter (076300333TF_PBLCATH53)	Class IIa	/	Certificate No. 1434-MDD-151/2020, PCBC 1434
Device 24 Zeus® CC- Cobalt Chromium Balloon Expanding Peripheral Stent System – OTW (076300333ZC_CoCrPSSSQ)	Class IIb implantable	/	Certificate No. 1434-MDD-486/2019, PCBC 1434
Device 25 Zeus® SX Plus - Nitinol Self Expanding Peripheral Stent System – OTW (076300333SX_PLSNTSSVJ)	Class IIb implantable	/	Certificate No. 1434-MDD-032/2021, PCBC 1434

Table 2: Devices covered by this letter and for which the NB is NOT yet 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 at the pre-application stage)	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
N/A			

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Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
29.04.2024	800011 / 24.87244	Initial issuance
26.07.2024	800011 / 24.107506	Rev01. Positive Transfer Assessment after signed Triparty agreement with TUV NORD POLSKA and submitted accompanying documents
14.11.2024	800011 / 24.124046	Rev02. Positive Transfer Assessment after signed Triparty agreement with PCBC and submitted accompanying documents