TÜVNORD

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TÜV®

Our / Your Reference	Contact	Direct Dial	Date
44 232 191525	medical@tuev-nord.de	Tel.:+49 201 825 2236	24 May 2024

Notified Body Confirmation Letter

Reference: EC-Certificate acc. 93/42/EEC Annex II without (4), No: 44 232 191525

Order no.: 8003072457

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, TÜV 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:

pro3dure medical GmbH
Am Burgberg 13
58642 Iserlohn
Germany
SRN Number: DE-MF-000000024

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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. Digital unterschrieben von Schmidt Caroline Datum: 2024.05.28 16:40:09 +02'00'

i. V. Caroline Schmidt
Deputy of Head of Project Management

Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

TÜVNORD i. V. Digital unterschrieben von Hoy Benjamin Datum: 2024.05.28 16:03:14 +02'00'

i. V. Dr. Benjamin Hoy
TIC Manager MDR

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
printodent® GR-10 guide	Class IIa	Generative Resin GR-10 guide	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
[redacted]	Class IIa	[redacted]	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
	Class IIa		93/42/EEC Annex II without (4), Certificate No: 44 232 191525
	Class IIa		93/42/EEC Annex II without (4), Certificate No: 44 232 191525
	Class IIa		93/42/EEC Annex II without (4), Certificate No: 44 232 191525
	Class IIa		93/42/EEC Annex II without (4), Certificate No: 44 232 191525
printodent® GR-14.1 denture	Class IIa	Generative Resin GR-14.1 denture	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
printodent® GR-14.2 denture HI	Class IIa	Generative Resin GR-14.1 denture	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
[redacted]	Class IIa	[redacted]	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
	Class IIa		93/42/EEC Annex II without (4), Certificate No: 44 232 191525
	Class IIa		93/42/EEC Annex II without (4), Certificate No: 44 232 191525
	Class IIa		93/42/EEC Annex II without (4), Certificate No: 44 232 191525
printodent® GR-17 temporary	Class IIa	Generative Resin GR-17 temporary	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
[redacted]	Class IIa	[redacted]	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
printodent® GR-17.1 temporary It	Class IIa	Generative Resin GR-17.1 temporary It	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
[redacted]	Class IIa	[redacted]	93/42/EEC Annex II without (4), Certificate No: 44 232 191525

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
[redacted]	Class IIa	[redacted]	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
	Class IIa		93/42/EEC Annex II without (4), Certificate No: 44 232 191525
printodent® GR-20 MJF	Class IIa	Generative Resin GR-20 MJF	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
THERMEO Powder	Class IIa	THERMEO Powder	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
THERMEO Liquid	Class IIa	THERMEO Liquid	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
THERMEO SO	Class IIa	THERMEO SO	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
THERMEO Blank	Class IIa	THEMEO Blank	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
[redacted]	Class IIa	[redacted]	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
	Class IIa		93/42/EEC Annex II without (4), Certificate No: 44 232 191525
	Class IIa		93/42/EEC Annex II without (4), Certificate No: 44 232 191525
	Class IIa		93/42/EEC Annex II without (4), Certificate No: 44 232 191525
otosil® ES-1.1 / 25 Shore	Class IIa	Otoplastik Silikon ES-1.1 /25	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
otosil® ES-1.1 / 40 Shore	Class IIa	Otoplastik Silikon ES-1.1 /40	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
otosil® ES-1.1 / 60 Shore	Class IIa	Otoplastik Silikon ES-1.1 /60	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
SysTherm PU	Class IIa	SysTherm PU	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
audioprint® GR-1	Class IIa	Generative Resin GR-1	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
audioprint® GR-10	Class IIa	Generative Resin GR-10	93/42/EEC Annex II without (4), Certificate No: 44 232 191525

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
audioprint® GR-11	Class IIa	Generative Resin GR-10	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
audioprint® L-1	Class IIa	UV Lacquer Coating L-1	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
audioprint® L-2 FLX	Class IIa	UV Lacquer Coating L-1	93/42/EEC Annex II without (4), Certificate No: 44 232 191525
Hand Pour Resin PR-1	Class IIa	Hand Pour Resin PR-1	93/42/EEC Annex II without (4), Certificate No: 44 232 191525

Table 2: Devices covered by this letter and for which the NB 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 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	N/A	N/A	93/42/EEC Annex II without (4), Certificate No: 44 232 191525 **Generative Resin GR-1 guide**
N/A	N/A	N/A	93/42/EEC Annex II without (4), Certificate No: 44 232 191525 **Generative Resin GR-19 OA**
N/A	N/A	N/A	93/42/EEC Annex II without (4), Certificate No: 44 232 191525 **THERMEO Powder/Liquid System**

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/24	00	Initial issue according to product list P111F007_Produktübersicht_pro3dure medical_30.04.2024_Rev03