TÜVNORD

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

SpofaDental a.s.
Markova 238, Holínské Predmestí 238
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Reference	Contact	Direct Dial	Date
No.: 44 232 141788 Order 8003070157	E-Mail: medical@tuev-nord.de	Tel.: +49 201 825 2236	10 April 2024

Notified Body Confirmation Letter
Reference: EC-Certificate acc. 93/42/EEC Annex II, No.: 44 232 141788
Order 8003070157

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:

SpofaDental a.s.
Markova 238, Holínské Predmestí 238
506 01 JICÍN
Czech Republic
SRN Number: CZ-MF-000000945

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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. Kevin Mühlenberg
Head of Project Management
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

TÜVNORD i. A.
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i. A. Klaus Jung
TIC Management
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

TÜVNORD

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
Adhesor ADHESOR, 80g PLV shade 1 + 55g LIQ (4111111PE) ADHESOR, 80g PLV shade 2 + 55g LIQ (4111112PE) ADHESOR, 80g PLV shade 1 (4111131PE) ADHESOR, 80g PL V shade 2 (4111132PE) ADHESOR, 55g LIQ (4111150PE)	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 44 232 141788; TÜV NORD CERT GmbH
Adhesor Carbofine ADHESOR CARBOFINE, 80g PLV + 40g LIQ (4111420PE) ADHESOR CARBOFINE, 40g LIQ (4111431PE)	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 44 232 141788; TÜV NORD CERT GmbH
Cavicide CaviCide 200 ml (4731221/15) CaviCide 700 ml (4731222/15) CaviCide 5 l (4731223)	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 44 232 141788; TÜV NORD CERT GmbH
Evicrol EVICROL (4121121PE)	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 44 232 141788; TÜV NORD CERT GmbH
Duracryl Plus DURACRYL PLUS LIQ. 250g (4316902)	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 44 232 141788; TÜV NORD CERT GmbH

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
DURACRYL PLUS PLV. 500g O (4316411) DURACRYL PLUS PLV. 500g U (4316412) DURACRYL PLUS PLV. 500g V (4316413) DURACRYL PLUS PLV. 500g Z (4316416)			
Kavitan CEM KAVITAN CEM, 20g PLV + 15g LIQ (4113270PE) KAVITAN CEM, 60g PLV + 45g LIQ (triple pack) (4113273PE) KAVITAN CEM**, 15g LIQ** (4113279PE)	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 44 232 141788; TÜV NORD CERT GmbH
Kavitan Plus KAVITAN PLUS, 15g PLV shade A2 + 15g LIQ (4113231PE) KAVITAN PLUS, 15g PLV shade A3 + 15g LIQ (4113232PE) KAVITAN PLUS, 15g LIQ (4113240PE)	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 44 232 141788; TÜV NORD CERT GmbH
Superacryl Plus SUPERACRYL PLUS PLV.500g O (4328411) SUPERACRYL PLUS PLV.500g U (4328412) SUPERACRYL PLUS PLV.500g V (4328413) SUPERACRYL PLUS PLV.500g Z (4328414)	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 44 232 141788; TÜV NORD CERT GmbH

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
SUPERACRYL PLUS PLV.500g X (4328417) SUPERACRYL PLUS LIQ.250g (4328902)			

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
Adhesor Fine	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 44 232 141788; TÜV NORD CERT GmbH
Premacryl Plus	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 44 232 141788; TÜV NORD CERT GmbH
Kavitan LC	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 44 232 141788; TÜV NORD CERT GmbH
Superpont C+B	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 44 232 141788; TÜV NORD CERT GmbH

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/04/10	Rev.0	Initial issue, P111F007 Rev.1