TÜVNORD

Katowice, 21.10.2024

TÜV NORD Polska Sp. z o.o
Mickiewicza 29
40-085 Katowice
Poland

Poldent Sp. z o.o.
Dzika 2
00-194 Warszawa
Poland

Notified Body Confirmation Letter
Reference: 26/24/1

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 Polska Sp. z o.o., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2274 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:

Poldent Sp. z o.o.
Dzika 2
00-194 Warszawa
Poland

SRN number: PL-MF-000005367

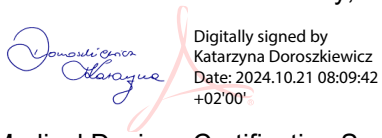
The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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,



Medical Devices Certification Specialist

Jowita Dyrda
Deputy Head of the Notified Body No. 2274 for Medical Devices
TÜV NORD Polska Sp. z o.o.

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**
Endostar Paste Fillers with safety spring (PFL) Basic UDI-DI: 5900261FILLYM	Class IIa	Endostar Igły do wypełniania kanału ze sprężynką bezpieczeństwa (PFL)	Certificate: TNP/MDD/0251/3772/2019 NB: 2274
Endostar Paste Fillers without spring (PFN) Basic UDI-DI: 5900261FILLYM	Class IIa	N/A	Certificate: TNP/MDD/0251/3772/2019 NB: 2274

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
Endostar Peeso Reamers Basic UDI-DI: 5900261ROTA4C	Class IIa	Endostar Poszerzacze Peeso	Certificate: TNP/MDD/0251/3772/2019 NB: 2274
Endostar Gates Glidden Basic UDI-DI: 5900261ROTA4C	Class IIa	Endostar Poszerzacze Gates	Certificate: TNP/MDD/0251/3772/2019 NB: 2274
Endostar Spreader Sonic Files Basic UDI-DI: 5900261ROTA4C	Class IIa	N/A	Certificate: TNP/MDD/0251/3772/2019 NB: 2274
Endostar NT2 Rotary System Basic UDI-DI: 5900261ROTA4C	Class IIa	Endostar NT2 NiTi Two Rotary System	Certificate: TNP/MDD/0251/3772/2019 NB: 2274
Endostar RE Endo Rotary System Basic UDI-DI: 5900261ROTA4C	Class IIa	Endostar RE Re Endo Rotary System	Certificate: TNP/MDD/0251/3772/2019 NB: 2274
Endostar E3 Rotary System (wersja/version: Basic) Basic UDI-DI: 5900261ROTA4C	Class IIa	Endostar E3 Basic Rotary System	Certificate: TNP/MDD/0251/3772/2019 NB: 2274
Endostar E3 Rotary System (wersja/version: Big) Basic UDI-DI: 5900261ROTA4C	Class IIa	Endostar E3 Big Apical Rotary System	Certificate: TNP/MDD/0251/3772/2019 NB: 2274

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Zarząd:
Dagmara Żygowska - Prezes Zarządu

NIP 634-10-14-590
REGON: 272557766
Sąd Rejonowy w Katowicach, KRS: 0000118633
Kapitał zakładowy: 850000 PLN

Konto bankowe:
mBank o. korporacyjny Katowice
02 1140 1078 0000 4042 4600 1001
EUR 72 1140 1078 0000 4042 4600 1002
USD 93 1140 1078 0000 4042 4600 1012

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
Endostar E3 Rotary System (wersja/version: Small) Basic UDI-DI: 5900261ROTA4C	Class IIa	Endostar E3 Small Apical Rotary System	Certificate: TNP/MDD/0251/3772/2019 NB: 2274
Endostar E3 Azure (wersje/versions: Basic, Small, Big) Basic UDI-DI: 5900261ROTA4C	Class IIa	N/A	Certificate: TNP/MDD/0251/3772/2019 NB: 2274
Endostar REvision Basic UDI-DI: 5900261ROTA4C	Class IIa	N/A	Certificate: TNP/MDD/0251/3772/2019 NB: 2274
Endostar EP Easy Path Basic UDI-DI 5900261ROTA4C	Class IIa	N/A	Certificate: TNP/MDD/0251/3772/2019 NB: 2274

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	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/10/21	26/24/1	Initial issue

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