

Katowice, 5 marca 2024

Jowita Dyrda
601 401 053
j.dyrda@tuv-nord.pl

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

To whom it may concern

We confirm that the contract for surveillance activities according to Article 120 (3e) of Regulation (EU) 2017/745 between Poldent Sp. z o.o., Dzika 2, 00-194 Warszawa and TÜV NORD Polska Sp. z o. o. (Notified Body No 2274), Mickiewicza 29, 40-085 Katowice was signed on 5.01.2024 r. The surveillance audit took place.

Devices covered by this letter for which the TÜV NORD Polska Sp. z o.o. is responsible for appropriate surveillance to 26.05.2024 r.:

1. Paste Fillers:

- [logo Endostar] Paste Fillers with safety spring (PFL)
- [logo Endostar] Paste Fillers without spring (PFN)

2. Instruments for canal irrigation and disinfection:

[logo Endostar] Spreader Sonic Files

3. Rotary Instruments:

- [logo Endostar] NT2 NiTi Two Rotary System
- [logo Endostar] RE Re Endo Rotary System
- [logo Endostar] E3 Basic Rotary System
- [logo Endostar] E3 Big Apical Rotary System
- [logo Endostar] E3 Small Apical Rotary System
- [logo Endostar] E3 Azure, wersje/versions Basic, Small, Big
- [logo Endostar] EP Easy Path
- [logo Endostar] REvision



DLA NASZEJ WSPÓLNEJ PRZYSZŁOŚCI TÜV NORD POLSKA PROWADZI NASADZENIA NOWYCH DRZEW I UŻYWA PAPIERU BIUROWEGO Z RECYKLINGU.

TÜV NORD Polska Sp. z o. o.

ul. Mickiewicza 29
40-085 Katowice
tel.: +48 32 786 46 46

biuro@tuv-nord.pl
www.tuv-nord.pl

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

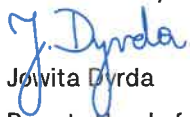
Strona 3 z 4

4. Enlargers:

- [logo Endostar] Peeso Reamers

- [logo Endostar] Gates Glidden

Your sincerely



Jowita Dyrda

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



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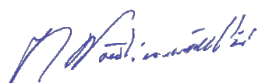
To whom it may concern,

In accordance with the Regulation (EU) 2023/607 of March 15th, 2023, we declare that our CE certificate no. TNP/MDD/O251/3772/2019, issued on 28-02-2019 and valid until 27-02-2024 has been unconditionally extended until 26-05-2024.

At the same time, we would like to inform you that we have entered the process of obtaining MDR certification for our devices, which means that the moment we sign an agreement with a Notified Body, we will be able to extend the validity of our current CE certificate until 31-12-2028.

Details of above statements could be verified either by checking the stipulations of EU Regulation of March 15th 2023 (<http://data.europa.eu/eli/reg/2023/607/oj>) and/or with our Notified Body or by contacting our Quality Assurance&Regulatory Affairs Team (k.machnikowska-buczak@poldent.pl)

Best regards,



Marek Niedzwiedzki
President&CEO, Poldent Co. Ltd