

Katowice, 13 czerwca 2023

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EMED SP. Z O. O. SP. K.
ul. Ryżowa 69a
05-816 Opacz-Kolonia
Poland

Statement of Notified Body 2274

At the request of the manufacturer EMED SP. Z O. O. SP. K. ul. Ryżowa 69a, 05-816 Opacz-Kolonia dated 10.04.2023 on behalf of the Notified Body TÜV NORD Polska Sp. z o.o. I declare that:

[1] EMED SP. Z O. O. SP. K. is in the conformity assessment process according to Regulation 2017/745 (MDR), Annex IX of the following medical devices:


- Electrosurgical units
- Endoscopic irrigation pump
- Monopolar electrodes
- Monopolar electrodes, argon, flexible
- Monopolar electrodes, argon, flexible, sterile
- Monopolar electrodes, argon, rigid
- Monopolar electrodes, argon, rigid, sterile
- Monopolar electrodes, sterile
- Laparoscope bipolar instruments
- Bipolar forceps for vessel sealing
- Bipolar electrodes
- Equipment for bipolar closing and cutting instruments – disposable
- Disposable fittings for bipolar closing and cutting instruments
- Disposable fittings for bipolar laparoscopic instruments
- Complete bipolar sealing and cutting instrument
- Bipolar forceps
- Monopolar handles
- Monopolar handles for smoke evacuation with electrode, sterile
- Monopolar handles with electrode, sterile
- Monopolar handles, argon
- Equipment for electrosurgical devices - neutral electrodes, disposable
- Equipment for electrosurgical devices - neutral electrodes, reusable

[2] The Notified Body TÜV NORD Polska Sp. z o.o. hereby undertakes to inform the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products about serious shortcomings related to safety identified during conformity assessment.

[3] The certificate with the number TNP/MDD/0320/4919/2020, issued by Notified Body No. 2274 on 24.05.2021, has not been withdrawn. The certificate will expire on 20.04.2023

[4] On the basis of the above information, the Notified Body confirms that the conditions for the renewal of the MDD certificate contained in the REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 amending Regulations (EU) 2017/745 on the issue of transition periods until 26.05.2024, are met.

With kind regards,



Kornel Lukaszczyk
Director of Notified Body No. 2274



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

TÜV NORD Polska Sp. z o. o.

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Kapitał zakładowy: 850000 PLN

Konto bankowe:
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EUR 72 1140 1078 0000 4042 4600 1002
USD 93 1140 1078 0000 4042 4600 1012

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