

CERTIFICATE

Management system as per
PN-EN ISO 13485:2016-04
Medical devices - Quality management systems - Requirements for regulatory purposes

In accordance with TÜV NORD Polska Sp. z o.o. procedures, it is hereby certified that

EMED SP. Z O.O. SP.K.
ul. Ryżowa 69a, PL / 05-816 Opacz-Kolonia

with the locations / sites according to the annex



applies a management system in line with the above standard for the following scope

**Design, production, sales and service of electrosurgical units,
accessories and endoscopic irrigation pump.**

Regardless of the fact that TÜV NORD Polska Sp. z o.o. is a notified body No. 2274 in the area of medical devices, this Certificate is not a Certificate of Conformity within the meaning of Directive 93/42/EEC and is not a basis for CE marking.

Certificate Registration No. **AC090 MD/1952/4919/2020**
Audit Report No. PL4919/2020

Valid from **21-04-2020**
Valid until **20-04-2023**



Manager of Certification Body
TÜV NORD Polska Sp. z o.o.

Katowice, 21-04-2020

This certification was conducted in accordance with the TÜV NORD Polska Sp. z o.o. auditing and certification procedures and is subject to regular surveillance audits.

TÜV NORD Polska Sp. z o.o.

ul. Mickiewicza 29

40-085 Katowice

www.tuv-nord.pl



AC 090

ANNEX

to Certificate Registration No.: **AC090 MD/1952/4919/2020**

EMED SP. Z O.O. SP.K.
ul. Ryżowa 69a, PL / 05-816 Opacz-Kolonia



Certificate Registration No.
AC090 MD/1952/4919/2020-001

Location
EMED SP. Z O.O. SP.K.
ul. Ryżowa 69, PL / 05-816 Opacz-Kolonia

Scope
Design, production and service of
electrosurgical units, accessories and
endoscopic irrigation pump.

AC090 MD/1952/4919/2020-002

EMED SP. Z O.O. SP.K.
ul. Ryżowa 84b, PL / 05-816 Opacz-Kolonia

Design and production of electrosurgical units,
accessories and endoscopic irrigation pump.

End of the List



Manager of Certification Body
TÜV NORD Polska Sp. z o.o.

Katowice, 21-04-2020

TÜV NORD Polska Sp. z o.o.

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