

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

Przedsiębiorstwo Elektroniki Profesjonalnej IGEL Jerzy Kowaliński ul. Chorzowska 64, PL / 44-100 Gliwice



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

Design, development, production and service of patient monitors.

 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/1827/4910/2019
 Valid from
 13-06-2022

 Audit Report No. PL4910/2022
 Valid until
 12-06-2025

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

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

Katowice, 26-05-2022

www.tuv-nord.pl