

# 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**  
mgr inż. 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**  
Audit Report No. PL4910/2019

Valid from **13-06-2019**  
Valid until **12-06-2022**



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

Katowice, 13-06-2019

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](http://www.tuv-nord.pl)



AC 090  
QMS