

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



FAMED Żywiec Sp. z o.o. ul. Fabryczna 1, PL / 34-300 Żywiec

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

Design, development, production, distribution and service of ICU beds. rehabilitation beds and hospital beds, delivery beds, baby cots, operating and treatment tables, gynecological and treatment chairs, patient transport trolleys, luminaires and relevant accessories.

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/1202/139/2016

Audit Report No. PL139/2019

Valid from 07-10-2019

Valid until

13-09-2022

Initial certification: 23-09-2016

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

Katowice, 07-10-2019

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.

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