

# 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

**Lubelskie Zakłady Farmaceutyczne  
"Polfa" Spółka Akcyjna  
ul. Wojciechowska 42, PL / 20-704 Lublin**

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

**Design, manufacturing and distribution of plastic medical devices.  
Ethylene oxide sterilization of medical devices in accordance with EN ISO 11135.**

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/1430/52/2016**  
Audit Report No. PL52/2021

Valid from **21-02-2022**  
Valid until **20-02-2025**



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

Katowice, 20-02-2022

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.