

# 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 placing on the market of plastic medical devices.  
Sterilization of medical devices with ethylene oxide in accordance with EN ISO 11135:2014.  
Contract sterilization with ethylene oxide in accordance with EN ISO 11135:2014.**

Certificate Registration No. **AC090 MD/1430/52/2016**  
Audit Report No. PL52/2022-12

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



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

Katowice, 13-03-2023

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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