

# 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

**OXYWISE, S.R.O.**  
Hurbanova 21, 921 01 Piešťany, Slovakia

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

**Design and development, placing on the market, production, service  
and maintenance of medical oxygen generating systems and filling/reduction ramps.**

Certificate Registration No. **AC090 MD/2047/5165/2021**  
Audit Report No. PL5165/2024

Valid from **08-04-2024**  
Valid until **07-04-2027**



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

Katowice, 08-04-2024

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.

Visit [https://listareferencyjna.tuv-nord.pl/Lista\\_Referencyjna.php](https://listareferencyjna.tuv-nord.pl/Lista_Referencyjna.php) to validate certificate authenticity.

TÜV NORD Polska Sp. z o.o.

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