

CERTIFICATE OF FREE SALE

Report No.	2022/003	Valid until	04.05.2027	Spis/File	6156/2022/1100
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Medical Device(s)	Generátor kyslíka PSA Oxygen Generator O10, O20, O40, O60, O70, O100, O190, O280, O430, O640, O880, O880X2, O1250, O1250X2, O1500, O1500X2		
UDI-DI	858800412000medical25	GMDN/EDMS	UMDNS 12883
Class	IIb	SIDC code	P85537
Certificate No.	10000462533-PA-NoMA-SVK	Valid Until	04.05.2027
Notified body No.	2460		
Notified Body (name)	DNV Product Assurance AS		
Notified Body (address)	Veritasveien 3, 1363 Høvik, NORWAY		

The **State Institute for Drug Control**, Kvetná 11, 825 08 Bratislava, Slovak Republic as the competent authority for issuance of a Certificate of Free Sale for medical device under paragraph 129, section 2, letter ad) of Act No. 362/2011 Coll., Regulation (EU) 2017/745 on Medical Devices hereby certifies that:

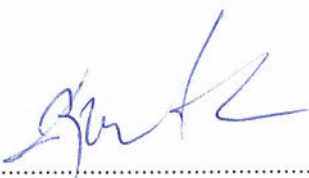
Manufacturer (name)	OXYMAT – Slovakia s.r.o.
Address	Vaňovce 87, 916 13 VAŇOVCE, Slovak Republic
National trade register number	36 668 311
SIDC registration number	SK-MF-22-0293
EUDAMED Actor ID/SRN	SK-MF-00019263

- meet(s) on the date of issue of this Certificate all legal requirements in order to be placed on the market in Slovakia and export of the Medical Device is not prohibited.
- comply with requirements of Act No. 362/2011 Coll. Slovak Republic and Council Directive 93/42/EEC and it is bearing the **CE marking**.


The Certificate of Free Sale is issued to the manufacturer established within the territory of the Slovak Republic on its request for the purposes of the medical device(s) export outside the EU Member States.

Date: 22th June 2022





 Ing. Ivan Bernát
 Head of the Medical Devices Section



 PharmDr. Peter Potúček, PhD., MSc.
 Director