Slovak Chamber of Commerce and Industry

# MANUFACTURING & FREE SALE CERTIFICATE No. 302853

**TO WHOM IT MAY CONCERN**

Pieter Wiemers

Digitaal ondertekend door Pieter Wiemers
Datum: 2022.01.06 09:36:18 +02'00'

UNDERSIGNED AUTHORITY

## SLOVENSKÁ OBCHODNÁ A PRIEMYSELNÁ KOMORA /SOPK/

*(SLOVAK CHAMBER OF COMMERCE AND INDUSTRY, /SCCI/),*

a public legal institution from the Law No.9 / 1992 Coll. as amended and revised, and on the basis of submitted documents

## HEREBY CERTIFIES THAT:

1) **A company OXYWISE, s.r.o.,** /hereinafter referred as "**Manufacturer**"/, headquartered in Hurbanova 21, **Piešťany,** Postcode 921 01, **Slovak Republic, ID no. 44 651 465,** is the limited liability company established under the laws of the Slovak Republic **on March 5, 2009** and registered in **the Business Register of the District Court Trnava, Section: Sro, Insert No.: 23387/T**, with the subject matter: **manufacture of machinery and equipment, wholesale, retail, repair and servicing of medical equipment.**

2) **Manufacturer** has its **Manufacturing Plant in Piešťany** (SK), which has been granted authorisation (license), **No. RUVZ/2016/01555/4/Ra-PPL** for **manufacturing of oxygen and nitrogen generators,** under **Articles 6(3)(g) and 13(4)(a) of the Act no. 355/2007 Coll.**, as amended, by the **Regional Public Health Authority Trnava**, (the state administration for health care and health protection in the Slovak Republic, EU), on **September 20, 2016.**.

3) **The MANUFACTURER and Medical Devices** (*hereinafter referred as* **"MDs"**) made in **the Manufacturing Plant** are registered in accordance with the **Act no. 362/2011 Coll.** with the **State Institute for Drug Control** ***(SIDC)*** - the Competent Authority for MDs in the Slovak Republic, EU.

4) **The MDs which are listed in the Annex, comply with the requirements and standards for the safety of medical devices as required by applicable legislation of the Slovak Republic and the European Union, i.e.:**

- **Act no. 355/2007 Coll.** on Protection, Support and Development of Public Health and on Amendments and Supplements to Certain Acts, as amended
- **Act no. 362/2011 Coll.** on medicines and medical devices and on amendments to certain laws, as amended;
- **Act no. 56/2018 Coll.** on product conformity assessment, making a determined product on the market and on the amendment of certain laws,
- **Gov. Regulation no. 582/2008 Coll**. as amended by **2015/2013 Coll.** laying down details on European technical requirements and conformity assessment procedures for medical devices (MDs) **Class IIb** under **Annex II of the Medical Device Directive no. 93/42/EEC** and **Directive no. 2011/65/EU;**

5) **The MANUFACTURER** is the holder of **the EC Certificate of Quality Management System** *(No.260979-2018-AQ-CZS-RvA)*, according to the standard **ISO 9001:2015,** (*valid by April 25, 2021*), issued by **DNV GL - Business Assurance Czech Republic s.r.o. Prague, CZ (AB no. RiA C 024, NL)** and **the Management System Certificate for design and development, sale, production and installation, service and maintenance of medical oxygen generating systems and filling/reduction ramps** *(No. 258652-2018-AQ-CZS-NA-Ps Rev.0.0)*, according the standard **EN ISO 13485:2016** (*valid by April 7, 2021*), issued by **DNV GL & NEMKO PRESAFE AS, Høvik (NO), (CB no.MSD-CO-078 by NO-Accreditation MSYS 018).**

6) **The MANUFACTURER has prepared technical documentation and affixed the CE mark with the MDs specified in the Annex according to Annex II of the MDD no. 93/42/EEC, as amended, therefore the MDs maybe freely sold in all member states of the European Economic Area including the Slovak Republic.**

7) **This Manufacturing & Free Sales Certificate is issued to the MANUFACTURER on its request. Export of the MDs outside EU is not prohibited.**

**Bratislava,** 14 -06- 2018

*(Place and date)*

SLOVENSKÁ OBCHODNÁ A PRIEMYSELNÁ KOMORA SLOVAK CHAMBER OF COMMERCE AND INDUSTRY

*Certif. Seal*

Juraj Knopp

*(Name, signature of competent officer of SCCI)*

**Annex to M&FSC:**

# LIST OF MEDICAL DEVICES

**OXYWISE, s.r.o., Piešťany, Slovakia (SK) -** /MANUFACTURER/

| *Item:* | *List of medical devices (MDs)* | | ***SIDC*** *Reg. no.* | *MD Class* | *EC Declaration of Conformity (EC DoC) / datum of issue* |
|---|---|---|---|---|---|
| | *Product description* | *Product Name/ Model* | | | |
| 1 | Medical **Oxygen generator** *(UMDNS 12883) in 29 standard models with capacity ranging from 0, 4 to 150 Nm³/hour up to 95% purity.* | **Oxygen generator O1** | **P 98143** | **II b** | **EC DoC according the Medical Device Directive no. 93/42/EEC as amended, on May 28, 2018 and EC DoC No. 1700755/OXY/2017 according the Pressure Equipment Directive 2014/68/EU, Modules B+D, on 16/06/2017 both issued by OXYWISE, s.r.o. Piešťany (SK) – the Manufacturer** |
| | | **Oxygen generator O2** | | | |
| | | **Oxygen generator O4** | | | |
| | | **Oxygen generator O6** | | | |
| | | **Oxygen generator O9** | | | |
| | | **Oxygen generator O12** | | | |
| | | **Oxygen generator O15** | | | |
| | | **Oxygen generator O20** | | | |
| | | **Oxygen generator O20+** | | | |
| | | **Oxygen generator O27** | | | |
| | | **Oxygen generator O27+** | | | |
| | | **Oxygen generator O35** | | | |
| | | **Oxygen generator O35+** | | | |
| | | **Oxygen generator O50** | | | |
| | | **Oxygen generator O50+** | | | |
| | | **Oxygen generator O65** | | | |
| | | **Oxygen generator O65+** | | | |
| | | **Oxygen generator O80** | | | |
| | | **Oxygen generator O80+** | | | |
| | | **Oxygen generator O100** | | | |
| | | **Oxygen generator O100+** | | | |
| | | **Oxygen generator O125** | | | |
| | | **Oxygen generator O125+** | | | |
| | | **Oxygen generator O150** | | | |
| | | **Oxygen generator O150+** | | | |
| | | **Oxygen generator O80T** | | | |
| | | **Oxygen generator O100T** | | | |
| | | **Oxygen generator O125T** | | | |
| | | **Oxygen generator O150T** | | | |

*Ba/14.06.2018/ Ing. J. Knopp, CSc./ Int. Coop. Dpt., SCCI/SOPK*