

# EU DECLARATION OF CONFORMITY - ORIGINAL MEDICAL DEVICE

No°: **O2019019**

This declaration of conformity is issued under the sole responsibility of the manufacturer.

## Name and address of the manufacturer

Manufacturer:

Oxymat A/S

Address: Fasanvej 18-20, DK-3200 Helsingør, Denmark

Manufacturing location:

Oxymat – Slovakia s.r.o.

Address: Vaďovce 87, 916 13 Vaďovce, Slovakia

## Object of the declaration

### Description of the pressure equipment

Product: **PSA Generator**

Description: **Oxygen Generator - Oxymat**

Product Type: **O430**

Serial number: **O2019019**

The mentioned product complies with the requirements mentioned below:

### Conformity with directives

☒ 93/42/EC Medical device directive

### Applied Harmonized Standards

The object of the declaration described above is in conformity with the relevant standards:

EN ISO 7396-1:2016, EN ISO 15001:2010, EN ISO 14971:2012, European Pharmacopoeia actual edition and other relevant ISO/EN standards mentioned in internal specification.

### Conformity assessment procedures followed

MDD 93/42/EC

Certificate no. 9887-2017-CE-CZS-NA-PS 0.0

Annex II

Classified as class IIb according to Annex IX, rule 11

The products are marked with CE 2460.

**CE 2460**

## Notified Body

Name: DNV Nemko Presafe AS

Address: Veritasveien 3, 1363 Høvik, Norway.

## Intended use of device

The oxygen generator is a device used individually or installed as a set along with a compressor, condensing drier, filters, air receiver and oxygen tank.

The oxygen generator is a pressure device made up of vessels, pipes, pneumatic valves, safety devices (relief valves) and a silencer. A control unit, a so-called control panel, with or without an oxygen sensor, also forms part of the generator. The vessels are filled with inert ceramic material, a so-called molecular sieve, zeolite, which serves for the separation of oxygen from the other gases. The generator does not come into direct contact with the patient.

The oxygen generator produces Oxygen 93 per Cent (a 93 percent concentration of oxygen is defined by the European Pharmacopoeia 7.1 Monograph Oxygen (93 per Cent) as 04/2011:2455: 90.0 % V/V to 96.0 % V/V of oxygen, the rest is formed mainly by argon and nitrogen.) from air compressed by pressure swing absorption (PSA), which is further utilized in healthcare as a replacement of medical oxygen.

It is meant for use in distribution systems of medical oxygen, which is usually distributed through the hospital grid. Can be used as Primary, Secondary or Reserve source of supply.

The oxygen generator can be combined with supply sources containing 100% medical oxygen (e.g. bottles or cryogenic vessels). The oxygen generator can be supplied along with a high-pressure oil-free compressor with a filling station able to fill 93-percent oxygen into bottles.

## Issuer

Place of issue: **Vaďovce 87, 916 13 Vaďovce, Slovakia**

CEO: Jesper Sjøgren

Signature:

Issue date: **0**

*[Handwritten signature]*



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