EU Declaration of Conformity

We,

Osmotex AG,
Schützenstrasse 3
8800 Thalwil, CH
CHRN-MF-20000660

Declare under our sole responsibility that the medical device products listed below

Article No.	RO-2021-OS-G/B/D/W, RO-2021-OM-G/B/D/W, RO-2021-OL-G/B/D/W, RO-2021-OX-G/B/D/W, RM-2021-OS-G/B/D/W, RM-2021-OM-G/B/D/W, RM-2021-OL-G/B/D/W, RM-2021-OX-G/B/D/W
Name	Osmotex Active Sterilising Face Mask®
Type	self-disinfecting Face Mask MP Class 1, Type IIR
Manufacturer	Osmotex AG, Schützenstr. 3, 8080 Thalwil, Schweiz

Meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

The medical device has been classified as a **Class I medical device** (Medical Mouth and Nasal Mask) in accordance with Annex I of Directive (EU) 2017/745, and it complies with the following applicable harmonized standards**: DIN EN14683:2019+AC:2019 (Type IIR)** - bacterial filtration efficiency, splash resistance, biocompatibility, and microbiological purity.

Because of the mask design, the standard is not applicable to determine breathability - Breathability has been confirmed in a clinical user evaluation.

Technical documentation that meets the requirements of the above-mentioned directive, Annex II and III, is available as proof. For the use and application of the aforementioned product, we expressly draw your attention to the fact that the instructions for use and the respectively applicable application and safety regulations must be strictly observed. Only the supplied electronic unit with Li battery (EN60335-1:2020-08) may be used for power supply. The user is solely responsible for any improper use.

Thalwil, 13.01.2022

Trond Heldal
Director R&D and Operations