EU Certificate of Conformity

We,

Sciema GmbH
An der Hayl 4
D-55130 Mainz, Deutschland

declare under our sole responsibility that the medical product listed below

Article No.:	OS-2301
Name:	Osmotex Sterilizer Mund- und Nasenschutzmaske
Type:	self-disinfecting Face Mask MP Class 1, Type IIR
Manufacturer:	Osmotex AG, Schützenstr. 3, 8080 Thalwil, Schweiz
BfARM-Reg.No..	00170204 v. 22.01.2021

is in conformity with the applicable provisions of Directive 93/42/EEC, amended and revised by Directive 2007/47/EEC. The evaluation has been carried out in accordance with Annex VII thereof.

The medical device has been classified as a Class I medical device in accordance with Annex IX of Directive 93/42/EEC, and conforms to the following applicable harmonized standards:

EN14683:2019+AC:2019 (IIR)

Technical documentation that meets the requirements of the above-mentioned directive, Annex VII, 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 IEC60086-4 compliant external Li battery may be used for power supply. The user is solely responsible for any improper use.

Mainz, 23.01.2021

Dr. Anke Pfützner
(Managing Director)

This declaration of conformity expires on 31.01.2023.