

Issued by (Name/Signature)
Alexis Ruin




Date
2024-05-28

Approved by (Name/Signature)
Adrian Liljefors



Date
2024-05-28

NOSA smell training, Declaration of Conformity

Manufacturer	NoseOption AB Surbrunnsgatan 42, 113 48 Stockholm, Sweden	
Actor ID/SRN	SE-MF-000025669	
Product	NOSA smell training	
Basic UDI-DI	73500817804NX	
UDI-DI	GTIN-13 Sellable: 07350081780395 GTIN-14 Transportation box: 17350081780392 GTIN-14 Pallet: 27350081780399	
Classification	Medical device	
Conformity Assessment Route	Class 1	
We herewith declare that the above-mentioned product meets the provisions of EU Regulation 2017/745 of the European Parliament and of the Council.		
Standards Applied		
Harmonised Standards	Not Harmonised	
EN ISO 13485:2016+A11:2021 ISO 15223-1:2021 SS-ISO 15223-2:2017 ISO 14971:2019 EN 62366-1:2015+A1:2020 SS-EN 143:2000 ISO 10993-1:2018 EN ISO 10993-5:2009 ISO 10993-10: 2010 ISO 10993-17:2023 ISO 10993-18:2020 ISO 18562-1:2017 ISO 18562-2:2017 ISO 18562-3:2017 ISO 18562-4:2017 ASTM D4169-16 SS-EN ISO 16890-4:2017 ISO 20417	ISO 10993-18: 2020+A1:2022 ISO 10993-1:2018	
EC Certificate	N/A	
Start of CE Marking	2023-11-10	
This EU declaration of conformity is issued under the sole responsibility of the Manufacturer.		
Signature		
Name	Adrian Liljefors	
Position	CEO	
Place	Stockholm, Sweden	
Date	2024-05-28	