

# EU Declaration of Conformity

## Legal Manufacturer:

MediDen A/S  
Østre Alle 102  
9000 Aalborg  
Denmark  
Phone: +45 88626969  
Email: salg@mediden.dk

The manufacturer hereby declares that the below mentioned medical devices (MD) are compliant with the EU regulation 2017/745 for medical devices class 1 and the EU legislation 2016/425, CAT III, type B for personal protection equipment (PPE).

## Medical device:

Intendet to be worn in the health care sector to protect patient and users from cross-contamination. Tested according to and complies with: EN455-1:2000, EN455-2:2015, EN455-3:2015, EN455-4:2009.

## Personal protection equipment:

Intendet to be worn in relevant working situations to protect user against contamination from substances of concern. Tested according to and complies with: EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016, EN 16523-1:2015+A1:2018.

EU type examination (modul B) and on-going conformity modul C2 is performed by notified body 2777: Satra Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin, D15 YN2P, Ireland. Certificate number: 2777/17447-02/E09-02.

 2777

## Products valid under this Declaration:

MediDen Nitril Classic – Medicinsk undersøgelses- og beskyttelsehandske. Pufferfri.

	Color	White	Blue	Black
Size	Pack size	100Pcs	100Pcs	100Pcs
XS	Item number / REF	NH/H/08-100XS	NH/B/08-100XS	NH/S/08-100XS
S		NH/H/08-100S	NH/B/08-100S	NH/S/08-100S
M		NH/H/08-100M	NH/B/08-100M	NH/S/08-100M
L		NH/H/08-100L	NH/B/08-100L	NH/S/08-100L
XL		NH/H/08-100XL	NH/B/08-100XL	NH/S/08-100XL
XXL		NH/H/08-100XXL	NH/B/08-100XXL	NH/S/08-100XXL

This Declaration of conformity is issued under the sole responsibility of legal manufacturer.

## Place and Date

19.9.2022

## Name and Titel

Nicolaj Klit, Director

## Signature

