EU Declaration of Conformity

Legal Manufacturer:
MediDen A/S
Fredrikstadvej 15
9200 Aalborg SV
Denmark
Phone: +45 88626969
Email: salg@mediden.dk

The manufacturer hereby declares that the below mentioned medical devices (MD) are complient with the EU regulation 2017/745 for medical devices class 1 and the EU ligislation 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 subtsances 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.

CE 2777

Products valid under this Declaration:
MediDen Nitril Pro – Medicinsk undersøgelses- og beskyttelseshandske. Pudderfri.

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

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

Place and Date	Name and Titel	Signature
14.2.2023	Nicolaj Klit, Director	Nicolaj Klit