Declaration of conformity according to Regulation (EU) 2017/745 and Regulation (EU) 2016/425

We,

ARNOWA GmbH
Kugelbreite 30
33154 Salzkotten
Germany

declare under our sole responsibility that the products listed below meet all provisions of Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2016/425 on personal protective equipment.

The products are

- class I medical products in accordance with Rule 1 and Rule 5, Annex VIII, Chapter III, and meet the applicable "General Safety and Performance Requirements" according to Annex I of Regulation (EU) 2017/745 and
- Personal protective equipment of category III according to Annex I and meet the "Essential Health and Safety Requirements" according to Annex II of Regulation (EU) 2016/425.

Conformity assessment procedure (EU) 2017/745: Annexes II and III
Conformity assessment procedure (EU) 2016/425: Annexes V and VII (module C2) or VIII (module D)

Notified Body: Number 2777, SATRA Technology Europe Limited

Basic UDI-DI: 426059752ARNOMEDNL

Applied Standards: EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 13485:2016, 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 and EN 16523-1:2015+A1:2018

Intended purpose: The intended purpose of examination gloves is the covering of hands of healthcare professionals during examination procedures involving contact with patient body surfaces and natural patient body orifices.
The device is intended for medical examinations by healthcare professionals as barrier against potentially infectious material and other contaminants. Examination gloves are not intended to come in contact with breached skin.
The device is single use only and reuse is neither endorsed nor approved. The device is intended to be used for a transient period of time only.

Validity: If no changes are made to the product, the declaration is valid for 5 years.

Product name	Art.-No.	Sizes	Certificate Number (Module B)
ARNOMED NITRIL WHITE	301	XS - XL	2777/11521-02/E02-01 2777/14815-03/E34-01 2777/10474-05/E26-01 2777/10469-04/E14-01 2777/10648-04/E00-00 2777/13038-09/E03-01
ARNOMED NITRIL BLUE	351	XS - XXL	
ARNOMED NITRIL WHITE 200er	309	S - XL	
ARNOMED NITRIL BLUE 200er	359	S - XL	
ARNOMED NITRIL BLACK 200er	399	S - XL	
ARNOMED NITRIL BLUE XTRA STRONG	352	S - XL	
ARNOMED NITRIL BLUE XTRA LONG	353	S - XL	
ARNOMED NITRIL MIDNIGHT BLACK	391	XS - XXL	
ARNOMED NITRIL BLACK XTRA STRONG	392	S - XL	
ARNOMED NITRIL OCEAN BLUE	381	S - XL	
ARNOMED NITRIL ICE BLUE	382	XS - XL	
ARNOMED NITRIL LAVENDER VIOLET	383	XS - XL	
ARNOMED NITRIL LAVA RED	384	XS - XL	
ARNOMED NITRIL BLOSSOM ROSE	385	XS - L	
ARNOMED NITRIL PEPPERMINT GREEN	386	XS - XL	
ARNOMED NITRIL MAGNOLIA PINK	387	XS - L	
ARNOMED NITRIL SUNFLOWER YELLOW	388	XS - L	
ARNOMED NITRIL LIME GREEN	389	XS - XL	
ARNOMED NITRIL XTRA PURE	354	S - XL	

Salzkotten, 28.02.2025

Daniel Müller
Managing Director
ARNOWA GmbH