

EU DECLARATION OF CONFORMITY

(In accordance with EN ISO/IEC 17050-1)

Declaration number: **DOCIP 1301899**
Name and address of manufacturer / EU-AR: **Medz Europe BV
Wiekenweg 41
3815 KL Amersfoort
Netherlands**



THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF:

Name and address of manufacturer: **Medz Europe BV
Wiekenweg 41
3815 KL Amersfoort
Netherlands**

Product identification: **Eurogloves solid nitrile powder free black 100pcs**

Size	Product code/UDI	EAN Dispenser	EAN Outer Case
S	306010	8716985060107	8716985060114
M	306020	8716985060206	8716985060213
L	306030	8716985060305	8716985060312
XL	306040	8716985060404	8716985060411

See appendix A for a list of all products covered by this declaration.

The product group mentioned above is intended to be worn on the hand during medical examinations and non-invasive procedures to provide a barrier between the patient and the medical professional.

With regard to Medical Device Regulation (EU) 2017/745 Annex VIII, this product group is classified as a Class I Medical Device per rules 1 and 5.

Following EU notified body Type-Examination Certificate 060/2020/0363, this product group complies with Personal Protective Equipment Regulation (EU) 2016/425 Annex II as a Category III product and is classified as a Type B product following testing in accordance with EN ISO 374-1:2016+A1:2018.

THE PRODUCTS MENTIONED IN THIS DECLARATION ARE IN CONFORMITY WITH:

EU Community Legislation **Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]
Personal Protective Equipment (PPE) Regulation (EU) 2016/425 [OJEU L81/51-98, 31.03.2016]**

Harmonised standards **Medical devices**
EN 455-1:2020
EN 455-2:2015
EN 455-3:2015
EN 455-4:2009
EN ISO 13485:2016 + AC:2018
Personal protective equipment
EN ISO 21420:2020+EN 420:2003+A1:2009
EN ISO 374-1:2016+A1:2018
EN ISO 374-2:2019
EN ISO 374-4:2019
EN ISO 374-5:2016

Other specifications: **AQL ≤ 1.5
ASTM**

Notified Body: **Satra Technology Europe Limited (2777)
Bracetown Business Park, Clonee, Dublin 15, D15 YN2P, Ireland**

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Additional information:

Chemicals	Performance level EN ISO 374- 1:2016+A1:2018/Type B	Mean Degradation EN ISO 374-4:2019
K= 40% Sodium Hydroxide	6	-55%
P= 30% Hydrogen Peroxide	3	38.3%
T= 37% Formaldehyde	6	33.9%

Performance level	1	2	3	4	5	6
Breakthrough time (minutes)	>10	>30	>60	>120	>240	>480

Test results are based on palm thickness.

Tested for resistance to penetration according to EN ISO 374-2:2019

EN ISO 374-4:2019 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

Tested for resistance to penetration by bloodborne pathogens according to ASTM.

SIGNED FOR AND ON BEHALF OF:

Place and date of issue: **Amersfoort, 1 June 2021**

Signature:



Name, function: **D.P.J. Schmits, Operational Director**

N.S. van Voorst, Management Assistant

Company name: **Medz Europe BV**

Medz Europe BV

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APPENDIX A – list of products

The following products are covered by EU declaration of conformity DOCIP 1301899:

Eurogloves solid nitrile powder free blue 100pcs

Size	Product code/UDI	EAN Dispenser	EAN Outer Case
S	305010	8716985050108	8716985050115
M	305020	8716985050207	8716985050214
L	305030	8716985050306	8716985050313
XL	305040	8716985050405	8716985050412
XXL	305050	8716985050504	8716985050511