

# EU DECLARATION OF CONFORMITY

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

Declaration number: **DOCIP 1308649**  
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 soft nitrile powder free black 100pcs**

Size	Product code/UDI	EAN Dispenser	EAN Outer Case
<b>XS</b>	602400	8716985124007	8716985124014
<b>S</b>	602410	8716985024109	8716985024116
<b>M</b>	602420	8716985024208	8716985024215
<b>L</b>	602430	8716985024307	8716985024314
<b>XL</b>	602440	8716985024406	8716985024413

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 060/2018/2151, 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 C 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 C	Mean Degradation EN ISO 374-4:2019
K= 40% Sodium Hydroxide	6	-6.7%
P= 30% Hydrogen Peroxide	1	37.0%
T= 37% Formaldehyde	6	38.5%

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 1308649:

### Eurogloves soft nitrile powder free blue 100pcs

Size	Product code/UDI	EAN Dispenser	EAN Outer Case
S	603160	8716985031602	8716985031619
M	603170	8716985031701	8716985031718
L	603180	8716985031800	8716985031817
XL	603190	8716985031909	8716985031916

### Eurogloves soft nitrile powder free blue 200pcs

Size	Product code/UDI	EAN Dispenser	EAN Outer Case
XS	603100	8716985031008	8716985031015
S	603110	8716985031107	8716985031114
M	603120	8716985031206	8716985031213
L	603130	8716985031305	8716985031312
XL	603140	8716985031404	8716985031411