EU DECLARATION OF CONFORMITY

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

Declaration number: **DOCIP 1309783**

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 vinyl powder free clear 100pcs**

Size	Product code/UDI	EAN Dispenser	EAN Outer Case
XS	307000	8716985070007	8716985070014
S	307010	8716985070106	8716985070113
M	307020	8716985070205	8716985070212
L	307030	8716985070304	8716985070311
XL	307040	8716985070403	8716985070410

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 2777/15019-02/E00-00, 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 374-4:2019
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	-41,7%
P= 30% Hydrogen Peroxide	6	-45,4%
T= 37% Formaldehyde	5	-25,6%

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 374-4:2019.
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**