



EU Declaration of Conformity

Legal Manufacturer

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- Single Registration Number (SRN), if applicable	DK-MF-000002482	

Medical Device(s)

- Basic UDI-DI	570353800MeNF-00I-06010CK
- Product/trade name(s) and/or product code(s) (REF)/and or catalogue number	Nitrile Medical Examination Gloves, Powder-Free
- Other ref. allowing identification (e.g. UDI-DI)	-
- Intended Purpose	Nitrile Examination gloves are intended to be worn by healthcare practitioners to protect patient and user from cross-contamination.
- Risk classification	Class 1 according to rule no. 5 in MDR annex VIII

Other information (if applicable)

- Common Specifications used for compliance	
- Notified Body name and identification no. and description of the conformity assessment procedure performed	Centexbel Technologiepark 70, BE 9052 Gent Belgium
- Additional information	EU Type Examination Module B by Notified Body 0493 and On-going conformity Module D performed by notified body 0598 SGS Fimko Oy. EU Type Examination certificate issued by NB 0493: Ref. certificate 045/2019/0022.03
- Standards used to assure compliance	EU 2016/425, EN374-1:2016, Type C, EN374-4:2013, EN374-5:2016 Virus, EN16523-1:2015

The above mentioned manufacturer hereby declares that the above mentioned medical device(s) are compliant with the EU Regulation 2017/745 for Medical Devices and the EU legislations mentioned under "additional information".

This Declaration of Conformity is issued under the sole responsibility of the above mentioned manufacturer.

Name and Function: Khalid Elamri, Global Category Manager Signature  Abena, Egelund 35, DK-6200 Aabenraa	Place and date of issue Aabenraa, DK, 11-05-2021
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Appendix I, List of products

Product Name	Item no.	UDI-DI	Intended Purpose
Classic Sensitive Nitrile Examination gloves powder free blue colour, 200 pcs	290495-290499	-	Protect patient and user from cross-contamination.
Classic Sensitive Nitrile Examination gloves powder free orange, pink, purple, green colour, 100 pcs	290710-714, 290720-724, 290730-734, 290740-744	-	Protect patient and user from cross-contamination.

Appendix II, List of applicable standards used

Product Name	Standards used
Nitrile Examination gloves powder free	EN 455-1:2002
Nitrile Examination gloves powder free	EN 455-2:2015
Nitrile Examination gloves powder free	EN 455-3:2015
Nitrile Examination gloves powder free	EN 455-4:2009
Nitrile Examination gloves powder free	EN374-1:2016
Nitrile Examination gloves powder free	EN374-2:2003
Nitrile Examination gloves powder free	EN374-4:2013
Nitrile Examination gloves powder free	EN374-5:2016
Nitrile Examination gloves powder free	EN16523-1:2015
Nitrile Examination gloves powder free	EN420:2003

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