



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	57035380MeNFL-00I-06001LS (long cuff) 570353800MeNF-00I-06003CN
- Product/trade name(s) and/or product code(s) (REF)/and or catalogue number	Nitril 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. 1 and 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	SATRA Technology Europe Limited Bracetown Business Park Clonee D15YN2P Ireland
- Additional information	EU Type Examination Module B and On-going conformity Module C2 performed by notified body 2777, SATRA Technology Europe Limited. Issued EU Type Examination certificate number 2777/11513-01/E01-01
- Standards used to assure compliance	EU 2016/425, EN374-1:2016, Type B, EN374-4:2013, EN374-5:2016 Virus, EN16523-1:2015

The above mentioned manufacturer hereby declare 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 	Place and date of issue Aabenraa, DK, 20-04-2021
Abena, Egelund 35, DK-6200 Aabenraa	

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Appendix I, List of products

Product Name	Item no.	UDI-DI	Intended Purpose
Excellent Nitril Examination gloves powder free white and blue colour, 100 pcs	3940-3944 3958-3961, 290423, 3945	-	Protect patient and user from cross-contamination.
Excellent Nitril Examination gloves powder free blue colour, 150 pcs	290425-290429	-	Protect patient and user from cross-contamination.
Excellent Nitril Examination gloves powder free blue colour, long cuff, 100 pcs	3924-3927, 290431	-	Protect patient and user from cross-contamination.

Appendix II, List of applicable standards used

Product Name	Standards used
Nitril Examination gloves powder free	EN 455-1:2002
Nitril Examination gloves powder free	EN 455-2:2015
Nitril Examination gloves powder free	EN 455-3:2015
Nitril Examination gloves powder free	EN 455-4:2009
Nitril Examination gloves powder free	EN374-1:2016
Nitril Examination gloves powder free	EN374-2:2003
Nitril Examination gloves powder free	EN374-4:2013
Nitril Examination gloves powder free	EN374-5:2016
Nitril Examination gloves powder free	EN16523-1:2015
Nitril Examination gloves powder free	EN421:2010
Nitril Examination gloves powder free	EN420:2003

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