



EU Declaration of Conformity

Legal Manufacturer

- Name	ABENA A/S	www.abena.com
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- Phone / fax / email / webpage	DK-6200 Aabenraa Denmark	Fax: +45 7462 9737 Mail: info@abena.com
- Single Registration Number (SRN), if applicable	DK-MF-000002482	

Medical Device(s)

- Basic UDI-DI	57035380MeNAf-00I-060013F
- Product/trade name(s) and/or product code(s) (REF)/and or catalogue number	Nitril Medical Examination Gloves, Accelerator and Powder-Free
- Other ref. allowing identification (e.g. UDI-DI)	-
- Intended Purpose	Nitrile Examination gloves are intended to be worn by health care 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 D performed by notified body 0598, SGS Fimko OY. EU Type Examination certificate issued by notified body 2777, SATRA Technology Europe Limited. Ref. certificate number 2777/10013-03/E10-01
- 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, 27-04-2021
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Appendix I, List of products

Product Name	Item no.	UDI-DI	Intended Purpose
Excellent Nitril Examination gloves Accelerator and powder free blue colour, 100 pcs	290400-290404	-	Protect patient and user from cross-contamination.
Excellent Nitril Examination gloves Accelerator and powder free blue colour, 150 pcs	290670-290674	-	Protect patient and user from cross-contamination.
Excellent Nitril Examination gloves Accelerator and powder free blue colour, long cuff, 100 pcs	290405-290409	-	Protect patient and user from cross-contamination.
Excellent Nitril Examination gloves Accelerator and powder free blue, 200 pcs, low derma	1000006803-1000006807	-	Protect patient and user from cross-contamination.
Excellent Nitril Examination gloves Accelerator and powder free blue, 100 pcs, low derma	1000008823-1000008819	-	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	EN420:2003

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