



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-06007CW
- 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 2777/10648/E17-01
- 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 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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Template Responsible: JOHO	Created: JOHO	Approved: ULDA
File: Abena DoC External MDR Black Nitrile	Revision/Version: 1.1	Date: 19-08-2020
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Appendix I, List of products

Product Name	Item no.	UDI-DI	Intended Purpose
Classic Nitril Examination gloves powder free black colour, 200 pcs	290437-290441	-	Protect patient and user from cross-contamination.
Classic Nitril Examination gloves powder free black colour, 100 pcs	290660-290664	-	Protect patient and user from cross-contamination.
Classic sensitive Nitril Examination gloves powder free blue and white colour, 100 pcs	290481-290485	-	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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