



## EU Declaration of Conformity

### Legal Manufacturer

- Name	ABENA A/S	www.abena.com
- Address	Egelund 35	Phone: +45 7431 1818
- 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	570353800MeNF-001-06006CU	
- 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 2777/11521-01/E12-02	
- 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: <b>Khalid Elamri, Global Category Manager</b> Signature 	<b>Place and date of issue</b>  Aabenraa, DK, 12-01-2023
Abena, Egelund 35, DK-6200 Aabenraa	

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## Appendix I, List of products

Product Name	Item no.	UDI-DI	Intended Purpose
Classic Nitril Examination gloves powder free blue colour 200 pcs and 100 pcs	1999902086-1999902090 1999905271-1999905275	-	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	EN374-2:2014
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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