



## Single 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)	DK-MF-000002482	

### Medical Device(s)


- Basic UDI-DI	Please see appendix I
- Product/trade name(s) and product code(s) (REF)/and or catalogue number	Please see appendix I
- Other ref. allowing identification (e.g. UDI-DI)	Please see appendix I
- Intended Purpose	Please see appendix I
- Conformity assessment:	MDR art. 52.7, annex II and annex III
- Risk classification	Class I according to rule no. 1 and 5 in MDR annex VIII

### Other information (if applicable)

- Common Specifications used for compliance	-
- Additional information	The device is also compliant to Personal Protective Equipment regulation (EU) 2016/425 under the mentioned notified body assessment.
- Notified Body name and identification no. and description of the conformity assessment procedure performed	CAT III CE certified at CE2777 SATRA Technology Europe, they issued Module B  EU type certificate : 2777/ 11578-02/E32-01 Module C2 on-going certification assessed by CE 2777 SATRA Technology Europe.
- Standards used to assure compliance	Please see appendix II

The above mentioned manufacturer hereby declares that the below 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, 26.04.2022
Abena, Egelund 35, DK-6200 Aabenraa	

Template Responsible: JOHO	Created: JOHO	Approved: ULDA
File: Single Medical-Exam-Nitril-Glove-Classic-long 1999911321-1999911325 MDR and PPE	Revision/Version: 1.0	Date: 26-08-2022
Copyright: Abena	Applicable SOP: n/a	Page 1/2



## Single EU Declaration of Conformity

### Appendix I, List of products

Product Name	Item no.	Basic UDI-DI	EMDN code	Intended Purpose
Classic Nitril Examination gloves powder free blue colour, long cuff 150 pcs	1999911321-1999911325	57135710MeNFL-00I-06007J6	T01020204	Protect patient and user from cross-contamination.

*expand list accordingly*

### Appendix II, List of applicable standards used

Product Name	Standards used
Nitril Examination gloves powder free	EN 455-1:2020 +A1:2022
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	EN ISO 374-1:2016 +A1:2018
Nitril Examination gloves powder free	EN 374-2:2003
Nitril Examination gloves powder free	EN 374-4:2013
Nitril Examination gloves powder free	EN ISO 374-5:2016
Nitril Examination gloves powder free	EN 16523-1:2015
Nitril Examination gloves powder free	EN 420:2003 +A1:2019
Nitril Examination gloves powder free	EN 421:2010 (ex. clause 4.3)

Template Responsible: JOHO	Created: JOHO	Approved: ULDA
File: Single Medical-Exam-Nitril-Glove-Classic-long 1999911321-1999911325 MDR and PPE	Revision/Version: 1.0	Date: 26-08-2022
Copyright: Abena	Applicable SOP: n/a	Page 2/2