



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)


- Intended Purpose	Protect patient and user from cross-contamination
- Product/trade name(s) and product code(s) (REF)/and or catalogue number	Please see appendix I
- Basic UDI-DI	Please see appendix I
- Other ref. allowing identification (e.g. UDI-DI)	Please see appendix I
- EMDN (no. and term)	Please see appendix I
- Risk classification	Class I according to rule no. 1 and 5, MDR annex VIII
- Conformity route	MDR annex II and III

Other information (if applicable)

- Common Specifications used for compliance	-
- Compliance to other legislations	PPE Regulation EU 2016/425
- Notified Body name and identification no. and description of the conformity assessment procedure performed	Notified body 2777 Satra Technology issued Module B PPE CE certificate 2777/11578-03/E01-01. and On-going conformity module C2 certificate
- Additional information	-
- Standards used to assure compliance	Please see appendix II

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 legislations mentioned "Compliance to other legislations".

This Declaration of Conformity is issued under the sole responsibility of the above mentioned manufacturer.

Name and Function: Jakob Lei, Category Manager Signature 	Place and date of issue Aabenraa, DK, 17-10-2023
Abena, Egelund 35, DK-6200 Aabenraa	

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Appendix I, List of products

Product Name	EMDN no	EMDN term description	Item no.	Basic UDI-DI
Classic Protect Nitril Examination gloves powder free blue and white colour 150 pcs	T01020204	Nitrile Examination / Treatment gloves	290417-290421 290411-290415	570353800MeNF-00I-06009D2
Classic Protect Nitril Examination gloves powder free blue and white colour 200 pcs	T01020204	Nitrile Examination / Treatment gloves	290810-290814 290820-290824	570353800MeNF-00I-06009D2
Classic Protect Nitril Examination gloves powder free blue and white colour 100 pcs	T01020204	Nitrile Examination / Treatment gloves	290830-290834 290840-290844	570353800MeNF-00I-06009D2
Classic Protect Nitril Examination gloves powder free blue colour, long cuff 150 pcs	T01020204	Nitrile Examination / Treatment gloves	1999911321- 1999911325	57135710MeNFL-00I-06007J6

Appendix II, List of applicable standards used

Standard title	No. and year
Medical gloves for single use Requirements and testing for freedom from holes	EN 455-1:2020
Medical gloves for single use Requirements and testing for physical properties	EN 455-2:2015
Medical gloves for single use Requirements and testing for biological evaluation	EN 455-3:2015
Medical gloves for single use Requirements and testing for shelf life determination	EN 455-4:2009
Protective gloves against dangerous chemicals and micro-organisms Terminology and performance requirements for chemical risk	EN ISO 374-1:2016
Protective gloves against dangerous chemicals and micro-organisms Determination of resistance to degradation by chemicals	EN ISO 374-4:2019
Protective gloves against dangerous chemicals and micro-organisms Terminology and performance requirements for micro-organisms risks	EN ISO 374-5:2016
Determination of material resistance to permeation by chemicals Permeation by potentially hazardous liquid chemicals under conditions of continuous contact	EN 16523-1:2015
Protective gloves. General requirements and test methods	EN ISO 21420:2020
Protective gloves against ionizing radiation and radioactive contamination	EN 421:2010 (ex. 4.3)

expand list accordingly

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