



Single EU Declaration of Conformity

Legal Manufacturer

- Name	ABENA A/S	www.abena.com
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- 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 2777/21024-02/E17-01. and On-going conformity module D 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, 09-02-2024
Abena, Egelund 35, DK-6200 Aabenraa	

Template Responsible: JOHO	Created: JOHO
File: medical-Exam-Nitrile-Glove-Classic 1999902086-89,1999905271-75,290481-851999912582-86,1999917574-578,17839,290437-441	Revision/Version: 1.5
Copyright: Abena	Applicable SOP: n/a



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Appendix I, List of products

Product Name	EMDN no	EMDN term description	Item no.	Basic UDI-DI
Abena Classic Nitril Examination gloves powder free blue colour 200 pcs and 100 pcs	T01020204	Nitrile Examination / Treatment gloves	1999902086-1999902090 1999905271-1999905275	570353800MeNF-00I-06006CU
Abena Classic Nitril Examination gloves powder free black colour, 100 pcs	T01020204	Nitrile Examination / Treatment gloves	290481-290485	570353800MeNF-00I-06007CW
Abena Classic Nitril Examination gloves powder free white colour, 100 pcs and 200 pcs	T01020204	Nitrile Examination / Treatment gloves	1999912582-1999912586 1999914142-1999914147	570353800MeNF-00I-06006CU
Abena Classic, Nitrile, Powder-Free, Finger Textured, Blue, 100 pcs, long cuff	T01020204	Nitrile Examination / Treatment gloves	1999917574- 1999917578,1999917839	570353800MeNF-00I-06006CU
Abena Classic Nitril Examination gloves powder free black colour, 200 pcs	T01020204	Nitrile Examination / Treatment gloves	290437-290441	570353800MeNF-00I-06007CW

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 455-3:2024
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
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Standard title	No. and year
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

expand list accordingly

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