EU Declaration of Conformity

Legal Manufacturer

- Name - Address - Phone / fax / email / webpage	ABENA A/S Egelund 35 DK-6200 Aabenraa Denmark	www.abena.com Phone: +45 7431 1818 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+ 5, MDR annex VIII
- Conformity route	MDR annex II and III

Other information (if applicable)

- Common Specifications used for compliance	-
- Compliance to other legislations	EU 2016/425
- Notified Body name and identification no. and description of the conformity assessment procedure performed	EU Type Examination Module B and On-going conformity Module D performed by notified body 2777, SATRA Technology Europe Limited. Issued EU Type Examination certificate number 2777/10467-05/E16-01.
- Additional information	CAT III
- Standards used to assure compliance	-

The above mention 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, Global Category Manager
Signature

Abena, Egelund 35, DK-6200 Aabenraa

Place and date of issue

Aabenraa, DK, 30-01-2025

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Appendix I, List of products

Product Name	EMDN no	EMDN term description	Item no.	Basic UDI-DI
Latex Medical Examination Gloves, Powder Free, natural color size XS-XL	T010201	Latex Examination/ Treatment glove	881799, 438799, 438899,438999,438199	570353800MeLF-00I-06005AG

expand list accordingly

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 455-2:2023
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
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

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