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), if applicable	DK-MF-000002482	

Medical Device(s)

- Basic UDI-DI	Please see appendix I
- Product/trade name(s) and/or 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
- Risk classification	Class 1 according to rule no. 1 and 5 in MDR annex VIII

Other information (if applicable)

- Common Specifications used for compliance	n/a
- 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	PPE Regulation (EU) 2016/425 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 2777/17447-02/E01-01
- Standards used to assure compliance	Please see appendix II

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 EU legislations mentioned under “additional information”.
This Declaration of Conformity is issued under the sole responsibility of the above mentioned manufacturer.

Name and Function:
Khalid Elamri, Global Category Manager

Signature



Place and date of issue

Aabenraa, DK, 07-12-2021

Abena, Egelund 35, DK-6200 Aabenraa

Appendix I, List of products

Product Name	Item no.	Basic UDI-DI	Intended Purpose
Classic Nitril Examination gloves powder free blue colour 200 pcs and 100 pcs	1999902086-199992090 1999905271-1999905275	570353800MeNF-00I-06006CU	Protect patient and user from cross-contamination.

Appendix II, List of applicable standards used

Product Name	Standards used
Nitril Examination gloves powder free	EN 455-1:2020
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 16523-1:2015+ A1:2018
Nitril Examination gloves powder free	EN ISO 374-5:2016
Nitril Examination gloves powder free	EN 374-4:2019
Nitril Examination gloves powder free	EN ISO 21420:2020