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	Please see appendix I
- 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. I, MDR annex VIII
- Conformity route	MDR annex II and III

Other information (if applicable)

- Common Specifications used for compliance	N/A
- Compliance to other legislations	N/A
- Notified Body name and identification no. and description of the conformity assessment procedure performed	N/A
- Additional information	N/A
- 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

- EU Regulation 2017/745 on Medical Devices
- UK Medical Device Regulation 2002

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

Name and Function:
Tina Jønson, Global Category Manager
Signature

Place and date of issue
Aabenraa, DK, 14.06.2023

Abena, Egelund 35, DK-6200 Aabenraa

EU Declaration of Conformity

Appendix I, List of products

Product Name	Abena item no.	Intended Purpose	EMDN no	EMDN term description	Basic UDI-DI
Patient gown, S/M, Blue	210850	Patient gown with short sleeves. The gown is liquid repellent and is used for protection to avoid cross contamination, e.g. in presence of infectious diseases.	T0205	Non-Surgical gowns (excluding Protective equipment PPE)	57035380GoNSD-00I-06001YP
Patient gown, M/L, Blue	210851				
Patient gown, XL/XXL, Blue	210852				
Patient gown, M/L, Blue	1000011993				
Patient gown, XL/XXL, Blue	1000011992				
Patient gown, L, Blue	210810				
Protective gown, with cuff, neck ties, XL, Green	210932	Protective gown with cuff, neck and waist ties. The gown is liquid repellent and is used for protection to avoid cross contamination, e.g. in presence of infectious diseases.			
Protective gown, with cuff, neck ties, L, Green	210931				
Protective gown, with elastic, neck ties, L, Green	210900	Protective gown with elastic, neck and waist ties. The gown is liquid repellent and is used for protection to avoid cross contamination, e.g. in presence of infectious diseases.			
Protective gown, with elastic, neck ties, XL, Green	210901				
Protective gown, with elastic, neck ties, L, Blue	210902				
Protective gown, with elastic, neck ties, XL, Blue	210903				
Protective gown, with elastic, neck ties, L, Blue	240172				
Protective gown, with elastic, neck ties, L, Blue	210920				

EU Declaration of Conformity

Product Name	Abena item no.	Intended Purpose	EMDN no	EMDN term description	Basic UDI-DI
Protective gown, with elastic, neck ties, XL, Blue	210929				
Protective gown, with elastic fixation and thumbholes, L, Yellow	1000003492	Protective gown with elastic fixation and thumbholes. The gown is liquid repellent and is used for protection to avoid cross contamination, e.g. in presence of infectious diseases.			
Protective gown, with elastic fixation and thumbholes, L, Blue	1000003493				
Protective gown, with cuff, neck ties, L, Blue	210915	Protective gown with cuff, neck and waist ties. The gown is liquid repellent and is used for protection to avoid cross contamination, e.g. in presence of infectious diseases.			
Protective gown, with cuff, neck ties, XL, Blue	210916				
Protective gown, with cuff, hook-and-loop-tape closure, L, Blue	1010001523	Protective gown with cuff, hook-and-loop-tape closure and waist ties. The gown is liquid repellent and is used for protection to avoid cross contamination, e.g. in presence of infectious diseases.			
Protective gown, with cuff, hook-and-loop-tape closure, XL, Blue	1010001524				

EU Declaration of Conformity

Appendix II, List of applicable standards used

Standard title	**No. and year**
Medical devices – Quality management systems – Requirements for regulatory purposes	13485:2016
Medical devices – Application of risk management to medical devices	EN ISO 14971:2019
Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	EN ISO 15223-1:2021
Medical devices – Information to be supplied by the manufacturer	EN 20417:2021
Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	ISO 10993-1:2020
Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	ISO 10993-5:2009
Biological evaluation - Part 10: Tests for irritation and skin sensitization	ISO 10993-10:2013
Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	ISO 10993-12:2021

expand list accordingly