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	UK MDR 2002 (SI 2002 No 618, as amended)
- 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

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

Name and Function:
Tina Jønson, Global Category Manager
Signature

Abena, Egelund 35, DK-6200 Aabenraa

Place and date of issue

Aabenraa, DK, 26.03.2024

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Appendix I, List of products

Product Name	Abena item no.	Intended Purpose	EMDN no	EMDN term description	Basic UDI-DI
Bibs, Abena Classic, 3 ply, 70x38 cm, blue	330210	The product is used to minimize the risk of cross contamination for the healthcare staff and user by absorbing body liquids and food stuff.	T0299	Protection drapes and garments - Other	57035380BibDi-00I-06002JB
Bibs, Abena Classic, 3 ply, 60x38 cm, with pocket, white	330211				
Bibs, Abena Classic, 3 ply, 70x38 cm, with pocket, white	330212				
Bib, Abena Classic, 3 ply, 70x38cm, with pocket, round neck, white	1010002431				
Bib, Abena Classic, 2ply, 70x38 cm, with pocket, blue	1999914356				

Appendix II, List of applicable standards used

Standard title	No.
Medical devices – Quality management systems – Requirements for regulatory purposes	EN ISO 13485
Medical devices – Application of risk management to medical devices	EN ISO 14971
Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	EN ISO 15223-1
Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1
Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	EN ISO 10993-5
Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10

expand list accordingly