



## EU Declaration of Conformity

### Legal Manufacturer

- Name	ABENA A/S	www.abena.com
- Address	Egelund 35	Phone: +45 7431 1818
- Phone / fax / email / webpage	DK-6200 Aabenraa Denmark	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 Medical Device Regulation 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 mentioned 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: <b>Louise Risager, Global Category Manager</b> Signature <i>Louise Risager</i> Abena, Egelund 35, DK-6200 Aabenraa	<b>Place and date of issue</b> Aabenraa, DK, 28.03.2025
---	--

Template Responsible: JOHO	Created: JOHO	Approved: ULDA
File: DoC External MDR - Disposable adult bibs, SE, ver. 05	Revision/Version: 1.5	Date: 2022-11-02
Copyright: Abena	Applicable SOP: n/a	Page 1/2



## EU Declaration of Conformity

### Appendix I, List of products

Product Name	Abena item no.	Intended Purpose	EMDN no	EMDN term description	Basic UDI-DI
Apron, ABENA Classic, 37x78cm, tape on shoulders, white	1000024747	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-001-05002J4
Apron, ABENA Classic, 37x78cm, tape on shoulders + waist, white	1000024750				
Bibs, ABENA Classic, 2 ply, 70x37cm, tape, with pocket, white	1000024751				
Bibs, ABENA Classic, 2 ply, 70x37cm, neck-tie, with pocket, white	1000024752				

### Appendix II, List of applicable standards used

Standard title	No.
Quality management systems – Requirements	EN ISO 9001
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

*expand list accordingly*

Template Responsible: JOHO	Created: JOHO	Approved: ULDA
File: DoC External MDR - Disposable adult bibs, SE, ver. 05	Revision/Version: 1.5	Date: 2022-11-02
Copyright: Abena	Applicable SOP: n/a	Page 2/2