



## 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

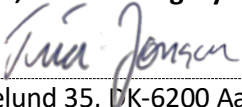
### Other information (if applicable)

- Common Specifications used for compliance	N/A
- Compliance to other legislations	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 mentioned 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: <b>Tina Jønson, Global Category Manager</b>	<b>Place and date of issue</b>
Signature 	Aabenraa, DK, 11.05.2023
Abena, Egelund 35, DK-6200 Aabenraa	

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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	330210	Disposable bib for adults. Used to minimize the risk of contamination for the healthcare staff and user by absorbing body liquids and food stuff. The bib is without pocket.	T0299	Protection drapes and garments - Other	57035380BibDi-00I-06002JB
Bibs, Abena Classic, 3 ply, 60x38 cm, with pocket	330211	Disposable bib for adults. Used to minimize the risk of contamination for the healthcare staff and user by absorbing body liquids and food stuff. The bib is with neck ties and reversable pocket.			
Bibs, Abena Classic, 3 ply, 70x38 cm, with pocket	330212				

### Appendix II, List of applicable standards used

Standard title	No. and year
Medical devices – Quality management systems – Requirements for regulatory purposes	EN ISO 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 15223-1:2016
Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2018
Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	EN ISO 10993-5:2009
Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2013

*expand list accordingly*

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