EU Declaration of Conformity

Legal Manufacturer

- Name - Address - Phone / fax / email / webpage	ABENA AB Ljungadalsgatan 19 SE-352 46 Växjö Sweden	www.abena.se Phone: +46 470 446 00 Mail: info@abena.se
- Single Registration Number (SRN)	SE-MF-000030220	

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.1, 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) MedDO (SR 812.213)
- 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 the EU Regulation 2017/745 for Medical Devices and the legislations mentioned "Compliance to other legislations".

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

Name and Function:
Sofia Lindell
PRRC

Signature Sofia Lindell

Place and date of issue
Sweden, Växjö, 2026.03.19

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Appendix I, List of products

Product Name	Abena item no.	EMDN no	EMDN term description	Basic UDI-DI
Bib with tape 37x70 cm	60090	T0299	Protection drapes and garments - Other	7331246BIAPX5
Bib with neck-tie 37x70 cm	60091			
Bib with neck-tie 37x70 cm	60092			
Bib with neck-tie 37x70 cm	60093			
Bib with neck-tie 37x70 cm	60094			
Bib with neck-tie 37x70 cm	60095			
Bio Bib with tape 37x70 cm	65003			
Bio Bib with neck-tie 37x70 cm	65004			
Bio Dental bib 39x44 cm	65001			
Bio Apron with tissue and film	65002			
Apron with tape 37x78 cm	60002			
Apron with tape 37x78 cm	60004			
Apron with tape 37x78 cm	60005			
Apron with tape 37x78 cm	60006			
Bio Dental bib 37x44 cm	65012			
Apron 70x143 cm	81213			
Dental bib TE91 46x60 cm	81281			
Bib with tape 37x70 cm	60097			
Bio Apron with tissue and film	6500201			
Bio Apron with tissue and film	6500202			
Bio Apron with tissue and film	6500203			
Bio Apron with tape 37x76,5 cm	6500204			
Bib with tape 37x70 cm	6009003			
Bib with tape 37x70 cm	6009004			

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Product Name	Abena item no.	EMDN no	EMDN term description	Basic UDI-DI
Bio Bib with adhesive tape	6500303			
Apron with tissue and PE-film 37x78 cm	1000024487			
Apron with tissue and PE-film 37x78 cm	1000024488			
Bib with adhesive tape 37x70 cm	1000024489			
Apron with tape 37x78cm with waist tape	1000024753			
Apron with tape 37x78cm	1000024754			
Bib with tape 37x70cm	1000024755			
Bib with neck-tie 37x70cm	1000024756			
Bib Finess neck-tie 37x70cm ISCC	1000031180			
Bib Finess tape 37x70cm ISCC	1000031181			
Apron Finess 37x78cm waist tape ISCC	1000031182			
Apron Abena Classic 37x78cm	1000031116			
Apron Abena Classic 37x78cm w/tape	1000031117			
Bib Abena Classic 37x70cm with tape	1000031118			
Bib Abena Classic 37x70cm with neck-tie	1000031119			

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Appendix II, List of applicable standards used

Standard title	No. and year
Medical Devices – Quality Management System – 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 medical devices labels, labelling and information to be supplied – Part 1: General requirements	EN ISO 15223
Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	EN ISO 10993
Quality Management System - requirements	EN ISO 9001
Environmental Management Systems – Requirements with guidance for use	EN ISO 14001