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, 2026.10.05

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Appendix I, List of products

Product Name	Item no.	Intended purpose	EMDN no	EMDN term description	Basic UDI-DI
Wash glove ALT PE 16x22cm	60061	The wipes, wash cloths, towels and wash gloves are reducing the risk for contamination for healthcare professionals and next user by absorbing leakage body liquids.	V9099	Various devices not included in other classes - other	7331246WIWA4X
Wash glove NW NP 16x22cm	60062				
Wash glove NW SD 16x22cm	60063				
Wash cloth Airlaid 20x26cm 125 sheets roll	60100				
Bio Washcloth T6p 19x25cm C-fold	65013				
BIO wash glove ALT 16x22cm	65020				
Wash cloth Wash cloth T6p 19x25cm C-fold	71349				
Wash cloth T6p 18x25cm C-fold	71359				
Wash cloth T6p 19x25cm C-fold	71601				
Wash cloth T6p 19x19cm plain	71603				
Wash cloth T6p 19x26cm plain	71604				
Wash cloth ALT 20x19cm C-fold	71615				
Wash cloth ALT 20x19cm C-fold	71617				
Handtowel ALT 48x50cm 4-fold	74089				
Wash cloth ALT 30x33cm M+Cross-fold	74093				
Wash cloth T3p 19x19cm plain	71622				
Wash cloth ALT 20x26cm plain	71623				
Wash cloth ALT 20x26cm plain	71624				
Wash cloth ALT 19x30cm ½ C-fold	60101				
Wash cloth T3p 19x19cm plain	71605				
Wash cloth ALT 20x26cm C-fold	71625				
Wash cloth T3p 18x25cm C-fold	71362				

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Product Name	Item no.	Intended purpose	EMDN no	EMDN term description	Basic UDI-DI
Wash cloth BIO ALT 19x30cm 1/2 C-fold	1000031413				
Wash cloth Tissue Plain 6-ply White 19x25	1000032332				
Wash cloth Tissue Plain 3-ply White 19x19	1000032334				
Washcloth Tissue Plain 6-ply White 18x25	1000032335				
Washcloth Tissue C-fold 6ply White 18x25	1000032336				
Washcloth Tissue Plain 6-ply White 18x19	1000032402				
Washcloth Tissue Plain 3-ply White 18x25	1000032403				
Washcloth Airlaid C-fold White 20x25	1000033287				
Washcloth Tissue Plain 6-ply 18x19	1000033288				
Washcloth T6p 18x25cm C-fold	1000032325				

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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