



EU Declaration of Conformity

Legal Manufacturer

- Name	ABENA A/S	www.abena.com
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- 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

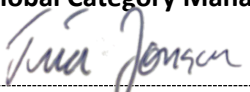
Other information (if applicable)

- 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: Tina Jønson, Global Category Manager	Place and date of issue Aabenraa, DK, 03.07.2023
Signature 	
Abena, Egelund 35, DK-6200 Aabenraa	

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File: DoC External MDR - Warming blanket, Duvet, Bed linen, <u>ver.</u> 03	Revision/Version: 1.5
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Appendix I, List of products

Product Name	Abena item no.	Intended Purpose	EMDN no	EMDN term description	Basic UDI-DI
Bed sheet, 240x150cm, White	210800	Single use bed sheet is liquid repellent and is used for protection to avoid cross contamination.	T030399	Heating covers - Other	57035380BeLiD-00I-06002V3
Bed sheet, ABENA Classic, 210x160 cm, green	1999915249				
Pillow case, 65x65cm, White	210801	Single use pillow case is liquid repellent and is used for protection to avoid cross contamination.			
Fitted sheet, 200x90x20cm, White	210802	Single use fitted sheet with elastic is liquid repellent and is used for protection to avoid cross contamination.			
Bed linen set (bed sheet, pillow case, fitted sheet), White	210803	Single use bed linen set (bed sheet, pillow case, fitted sheet) is liquid repellent and is used for protection to avoid cross contamination.			
Bed linen set (bed sheet, pillow case, fitted sheet), Green	210805				
Bed linen set (bed sheet, pillow case, Bed cover sheet)	1999915245				
Warming blanket, 220x110cm, Green	210807	Single use warming blanket is intended to reduce heat loss and for protection against cross contamination.			
Blanket, ABENA Classic, 110x110cm, green	1000001414				
Blanket, ABENA Classic, 220x150cm, green	1000001424				
Duvet, ABENA Classic, 220x128cm, white, polyester/SMS, non-sterile, ultrasonic, single use	1000010891	Single use duvet is intended to reduce heat loss and for protection against cross contamination.			

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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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