



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

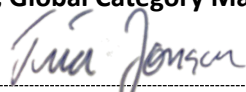
Other information (if applicable)

- Common Specifications used for compliance	ISO 9001:2015
- 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, 06.07.2023
Signature 	
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
Abri-Soft washable, 75x85 cm	4172	Abri-Soft Washable is used as a protective underpad for beds and mattresses The product has a breathable liquid safe barrier layer and is intended to absorb body fluids. Minimizes cross-contamination.	T04010201	Untuckable underpads	57035380UnPaW-00I-06001KG
Abri-Soft washable with handles, 75x85 cm	4174				
Abri-Soft washable PVC, 85x90 cm	407100				
Abri-Soft washable PVC, 85x90 cm	407200				
Abri-Soft washable, 85x90 cm	407300				
Abri-Soft washable, 75x85 cm	407500				
Abri-Soft washable, 90x210 cm	1000009139				
Abena Pad Breathable Washable, 90x85 cm	1000010503				
Abri-Soft washable, 75x85 cm	1000011886				
ABENA Washable Underpads, 85x75cm, light blue	1999915558				
ABENA Washable Underpads, 90x85cm, light blue	1999915559				
ABENA Washable Underpads, 85x75cm, light blue	1999915560				
ABENA Washable Underpads, 210x90cm, light blue	1999915561				
ABENA Washable Underpads, 85x75cm, light blue, with handle	1999915564				
Abri-Soft washable with flaps, 75x85 cm	4173		T04010202	Tuckable underpads	
Abri-Soft washable with flaps, 85x90 cm	407400				
ABENA Washable Underpads, 85x75cm, light blue, with flaps	1999915562				
ABENA Washable Underpads, 90x85cm, light blue, with flaps	1999915563				

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Product Name	Abena item no.	Intended Purpose	EMDN no	EMDN term description	Basic UDI-DI
Abena Pad Breathable Washable, 45x45 cm	1000003357	Protection of wheelchairs, car seats, and chairs. Intended to absorb body fluids. Minimizes cross-contamination	T04010299	Absorbent underpads - Other	

Appendix II, List of applicable standards used

Standard title	No. and year
Quality management systems – Requirements	EN ISO 9001:2015
Medical devices – Application of risk management to medical devices	EN ISO 14971:2019
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
Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	EN ISO 15223-1:2016
Medical devices – Information to be supplied by the manufacturer	EN 20417:2021

expand list accordingly

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