



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

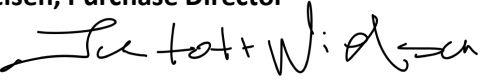
Other information (if applicable)

- Common Specifications used for compliance	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: Jan Toft Nielsen, Purchase Director	Place and date of issue Aabenraa, DK, 25.04.2024
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	The product is used as a protective, washable underpad for e.g. beds and chairs. Suitable for incontinent users. The use of washable underpads reduces the risk of 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					

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Product Name	Abena item no.	Intended Purpose	EMDN no	EMDN term description	Basic UDI-DI
ABENA Washable Underpads, 90x85cm, light blue, with flaps	1999915563				
Abena Pad Breathable Washable, 45x45 cm	1000003357		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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