



EU Declaration of Conformity

Legal Manufacturer

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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

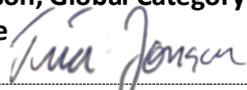
Other information (if applicable)

- 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, 30.03.2023
Signature 	
Abena, Egelund 35, DK-6200 Aabenraa	

Template Responsible: JOHO	Created: JOHO
File: DoC External MDR - Disposable fluff underpads, ver. 05	Revision/Version: 1.5
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Appendix I, List of products

Product Name	Abena item no.	EMDN no	EMDN term description	Basic UDI-DI	Intended Purpose
Abri-Soft Ultra Light 60x40cm	1000017876	T04010201	Untuckable underpads	57035380UnPaD-00I-05002YT	Abri-Soft is used as a protective, disposable underpad for e.g. beds and chairs. Suitable for incontinent users, but also for non-sterile procedures. The use of disposable underpads reduces the risk of contamination.
Abri-Soft Ultra Light 60x60cm	1000017868				
Abri-Soft Ultra Light 90x60cm	1000017869				
Abri-Soft Light 60x90cm	1000018312				
Abri-Soft Light 60x40cm	254116				
Abri-Soft Light 60x60cm	254117				
Abri-Soft Light 90x60cm	254118				
Abena Abri-Soft Basic 60x40cm	4116				
Abri-Soft Basic 60x60cm	4117				
Abri-Soft Basic 90x60cm	4118				
Abri-Soft Classic 60x40	4115				
Abri-Soft Classic 60x60cm	4119				
Abri-Soft Classic 75x60cm	4122				
Abri-Soft Classic 90x60cm	4123				
Abri-Soft Excellent 90x60cm	4109				
Abri-Soft Superdry 40x60 cm	254115				
Abri-Soft Superdry 60x60cm	254119				
Abri-Soft Superdry 90x60cm	254123				
Abena Abri-Soft Superdry 60x90	1000019801				
Abri-Soft Superdry 60x75	254122				
Extra soft disposable Abena Pad 60x60	254124				
Extra soft disposable Abena Pad 90x60	254125				

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EU Declaration of Conformity

Product Name	Abena item no.	EMDN no	EMDN term description	Basic UDI-DI	Intended Purpose
Abri-Soft Superdry, disposable underpad, 90x60cm, light blue	1000020018				
Abri-Soft Light, 90x60cm, light blue	1999909513				
Abri-Soft Superdry, 90x80cm	1000023480				
Bambo Nature Protective Mats, 60x90cm	1000023732				
Abri-Soft Superdry with flaps, 180x80cm	1000023479	T04010202	Tuckable underpads		

Appendix II, List of applicable standards used

Standard title	No. and year
Medical devices – Application of risk management to medical devices	ISO 14971:2019
Environmental management systems – Requirements with guidance for use	EN ISO 14001:2015
Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	ISO 15223-1:2021
Urine-absorbing aids — Part 1: Whole-product testing (Rothwell)	ISO 11948-1:1996
Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	ISO 10993-1:2018

expand list accordingly

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