



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. 1, 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 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: Tina Jønson, Global Category Manager Signature 	Place and date of issue Aabenraa, DK, 12.01.2023
Abena, Egelund 35, DK-6200 Aabenraa	

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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	T04010201	Untuckable underpads		
Abri-Soft Ultra Light 90x60cm	1000017869	T04010201	Untuckable underpads		
Abri-Soft Light 60x90cm	1000018312	T04010201	Untuckable underpads		
Abri-Soft Light 60x40cm	254116	T04010201	Untuckable underpads		
Abri-Soft Light 60x60cm	254117	T04010201	Untuckable underpads		
Abri-Soft Light 90x60cm	254118	T04010201	Untuckable underpads		
Abena Abri-Soft Basic 60x40cm	4116	T04010201	Untuckable underpads		
Abri-Soft Basic 60x60cm	4117	T04010201	Untuckable underpads		
Abri-Soft Basic 90x60cm	4118	T04010201	Untuckable underpads		
Abri-Soft Classic 60x40	4115	T04010201	Untuckable underpads		
Abri-Soft Classic 60x60cm	4119	T04010201	Untuckable underpads		
Abri-Soft Classic 75x60cm	4122	T04010201	Untuckable underpads		
Abri-Soft Classic 90x60cm	4123	T04010201	Untuckable underpads		
Abri-Soft Excellent 90x60cm	4109	T04010201	Untuckable underpads		
Abri-Soft Superdry 40x60 cm	254115	T04010201	Untuckable underpads		
Abri-Soft Superdry 60x60cm	254119	T04010201	Untuckable underpads		
Abri-Soft Superdry 90x60cm	254123	T04010201	Untuckable underpads		
Abena Abri-Soft Superdry 60x90	1000019801	T04010201	Untuckable underpads		
Abri-Soft Superdry 60x75	254122	T04010201	Untuckable underpads		
Extra soft disposable Abena Pad 60x60	254124	T04010201	Untuckable underpads		
Extra soft disposable Abena Pad 90x60	254125	T04010201	Untuckable underpads		

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Product Name	Abena item no.	EMDN no	EMDN term description	Basic UDI-DI	Intended Purpose
Abri-Soft Superdry, disposable underpad, 90x60cm, light blue	1000020018	T04010201	Untuckable underpads		
Abri-Soft Light, 90x60cm, light blue	1999909513	T04010201	Untuckable underpads		
Abri-Soft Superdry, 90x80cm	1000023480	T04010201	Untuckable underpads		
Abri-Soft Superdry with flaps, 180x80cm	1000023479	T04010202	Tuckable underpads		
Medicare Ultra Light, 60X90 cm	1000023941	T04010201	Untuckable underpads		
Medicare Light, 60X90 cm	1000023942	T04010201	Untuckable underpads		
Medicare Superdry, 80X180 cm	1000023943	T04010201	Untuckable underpads		
Medicare Basic, 60X90 cm	1000023975	T04010201	Untuckable underpads		
Medicare Superdry, 60X90 cm	1000023976	T04010201	Untuckable underpads		
Medicare Classic, 60X90 cm	1000023977	T04010201	Untuckable underpads		
Medicare Excellent, 60X90 cm	1000023978	T04010201	Untuckable underpads		
Medicare Superdry, 80X90 cm	1000023979	T04010201	Untuckable 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
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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