



EU Declaration of Conformity

Legal Manufacturer

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- Single Registration Number (SRN)	DK-MF-000002482	

Medical Device(s)

- Basic UDI-DI	Please see appendix I
- Product/trade name(s) and/or product code(s) (REF)/and or catalogue number	Please see appendix I
- Other ref. allowing identification (e.g. UDI-DI)	Please see appendix I
- Intended Purpose	Please see appendix I
- Risk classification	Class I according to rule no. 1 in MDR annex II

Other information (if applicable)

- Common Specifications used for compliance	ISO 9001:2015
- 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 EU legislations mentioned under "additional information".

This Declaration of Conformity is issued under the sole responsibility of the above mentioned manufacturer.

Name and Function: Ane Kirstine Schmidt, Category Manager	Place and date of issue
Signature 	Aabenraa, DK, 27.10.2021
Abena, Egelund 35, DK-6200 Aabenraa	

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Appendix I, List of products

Product Name	Item no.	Basic UDI-DI	Intended Purpose
Abri-Soft Ultra Light	1000017876	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	1000017868		
Abri-Soft Ultra Light	1000017869		
Abri-Soft Ultra Light	1000018312		
Abri-Soft Light	254116		
Abri-Soft Light	254117		
Abri-Soft Light	254118		
Abri-Soft Basic	4116		
Abri-Soft Basic	4117		
Abri-Soft Basic	4118		
Abri-Soft Classic	4115		
Abri-Soft Classic	4119		
Abri-Soft Classic	4122		
Abri-Soft Classic	4123		
Abri-Soft Excellent	4109		
Abri-Soft Superdry	254115		
Abri-Soft Superdry	254119		
Abri-Soft Superdry	254123		
Abri-Soft Superdry	1000019801		
Abri-Soft Superdry	254122		
Abena Pad Extra Soft Disposable	254124		
Abena Pad Extra Soft Disposable	254125		

Appendix II, List of applicable standards used

Product Name	Standards used
All products listed in Appendix 1	MDR EU 2017/745
	ENISO 14971:2019
	ISO10993-1:2018
	ISO10993-5:2009
	ISO10993-10:2013
	DS/EN 1041 + A1:2013
	ENISO15223-1:2016

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