



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

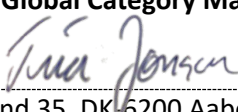
Other information (if applicable)

- Common Specifications used for compliance	N/A
- Compliance to other legislations	UK Medical Device Regulation 2002, SI 2002 No 618, as amended.
- 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

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
Signature 	Aabenraa, DK, 17.01.2024
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
Small Protective sheet, tissue and PE, 37x40cm	239096	Abena Small protective sheet is used for protection during non-sterile procedures such as, e.g. changing dressings and blood sampling.	T0210	Non-surgical drapes	57035380DrNSD-001-05001Y4
Small Protective sheet, tissue and PE, 37x50cm	239097				
ABENA Small Protective Sheets, 2-lags, 37x50cm, light blue, PE/tissue, single use	1000024421				
Abri-Bed Economy	246600	Protective sheets are used for the protection of e.g. beds and couches. The use of disposable protective sheets reduces the risk of contamination and improves hygiene.	T0499	Incontinence devices - other	57035380PrShD-001-05002AV
Abri-Bed Economy	246601				
Prot.sheet Abri-Bed Regular 140x80cm	246610				
Prot.sheet Abri-Bed Regular 175x80cm	246611				
Prot.sheet Abri-Bed Regular 210x80cm	246612				
Prot.sheet Abri-Bed Ultra Light 140x80cm	246650				
Prot.sheet Abri-Bed Ultra Light 170x80cm	246651				
Prot.sheet Abri-Bed Ultra Light 210x80cm	246652				
Abri-Bed Ultra Light	246653				
Prot.sheet Abri-Bed Light 140x80cm	246670				
Prot.sheet Abri-Bed Light 170x80cm	246671				
Prot.sheet Abri-Bed Light 210x80cm	246672				
Abri-Bed Light	246673				
Abri-Bed Light	246674				
Abri-Bed Light	246675				

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Prot.sheet Abri-Bed Super Soft 140x80cm	246720				
Prot.sheet Abri-Bed Super Soft 170x80cm	246721				
Prot.sheet Abri-Bed Super Soft 220x80cm	246722				
Abri-Bed Super Soft	246723				
Abri-Bed Basic	1000003695				
Abri-Bed Basic	1000003697				
ABENA Protective Sheet Standard , 2-ply, 80x170cm, light blue, PE/tissue, single use	1000024422				
ABENA Protective Sheet Standard, 2-ply, 80x210cm, light blue, PE/tissue, single use	1000024423				
ABENA Protective Sheet Reinforced, 3-ply, 80x170cm, white, PE/tissue, single use	1000024424				
ABENA Protective Sheet Reinforced, 3-ply, 80x210cm, white, PE/tissue, single use	1000024425				
ABENA Protective Sheet Super Soft, 2-ply, 80x170cm, white, airlaid/PE, single use	1000024426				
ABENA Protective Sheet Super Soft, 2-ply, 80x210cm, white, airlaid/PE, single use	1000024427				

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Appendix II, List of applicable standards used

Standard title	No. and year
Quality management systems – Requirements	EN ISO 9001
Medical devices – Quality management systems – Requirements for regulatory purposes	EN ISO 13485
Medical devices – Application of risk management to medical devices	EN ISO 14971
Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	EN ISO 15223-1

expand list accordingly

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