



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

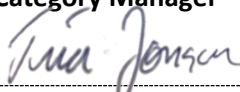
Other information (if applicable)

- Common Specifications used for compliance	N/A
- 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, 06.07.2023
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
Underpad Abri-Cell 6-ply 60x40cm	4176	Abri-Cell is used as a protective disposable underpad for e.g. beds and chairs. It is suitable for non-sterile procedures, such as wound care and blood tests, but it can also be used for incontinent users. The use of disposable underpads reduces the risk of contamination.	T04010201	Untuckable underpads	57035380UnPaD-001-06003Z4
Underpad Abri-Cell 6-ply 90x60cm	4177				
Underpad Abri-Cell 8-ply 60x30cm	330220				
Underpad Abri-Cell 8-ply 70x30cm	330221				
Underpad Abri-Cell 8-ply 60x40cm	330222				
Abri-Cell, disposable tissue underpad, 60x60cm	330223				
Underpad Abri-Cell 8-ply 90x60cm	330224				
Underpad Abri-Cell 6-ply 60x60cm	330225				
Abri-Cell, disposable tissue underpad, 60x60cm	330226				
Underpad Abri-Cell 10-ply 90x60cm	330227				
Underpad Abri-Cell 12-ply 90x60cm	330228				
Abri-Cell, disposable tissue underpad, 60x40cm	1000008217				
Abri-Cell, disposable tissue underpad, 90x60cm	1000008218				
ABENA Tissue Underpads, 6-ply, 60x40cm, light blue	1999915542	Abena tissue underpad is used as a protective disposable underpad for e.g. beds and chairs. It is suitable for non-sterile procedures, such as wound care and blood tests, but it can also be used for incontinent users. The use of disposable underpads reduces the risk of contamination.			
ABENA Tissue Underpads, 6-ply, 90x60cm, light blue	1999915543				
ABENA Tissue Underpads, 8-ply, 60x30cm, light blue	1999915544				
ABENA Tissue Underpads, 8-ply, 90x60cm, light blue	1999915545				
ABENA Tissue Underpads, 6-ply, 60x60cm, light blue	1999915546				

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Appendix II, List of applicable standards used

Standard title	No. and year
Medical devices – Quality management systems – Requirements for regulatory purposes	EN ISO 13485:2016
Medical devices – Application of risk management to medical devices	EN ISO 14971:2019
Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	EN ISO 15223-1:2021
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

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