



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)

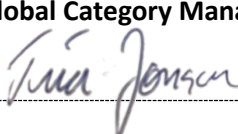
- Intended Purpose	Please see appendix I
- Product/trade name(s) and product code(s) (REF)/and or catalogue number	Please see appendix I
- Basic UDI-DI	Please see appendix I
- Other ref. allowing identification (e.g. UDI-DI)	Please see appendix I
- EMDN (no. and term)	Please see appendix I
- Risk classification	Class I according to rule no. 1, 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 MDR 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 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	Place and date of issue DK, Aabenraa, 30.01.2024
Signature 	

Template Responsible: JOHO	Created: JOHO	Approved: ULDA
File: DoC External MDR - Underpants, Colonoscopy pants, skirt ver. 04	Revision/Version: 1.5	Date: 2022-11-02
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Appendix I, List of products

Product Name	Abena item no.	OEM item no.	Intended Purpose	EMDN no	EMDN term description	Basic UDI-DI
Underpants, M/L, Blue	210853	210853	Used for protection of patient pre, during and post examinations or procedures.	T0299	Protection drapes and garments - Other	57035380PantD-00I-06001W9
Underpants, XL/2XL, Blue	1000002893	1000002893				
Underpants with hook-and-loop-tape closure, S/M, Blue	1000001839	1000001839				
Underpants with hook-and-loop-tape closure, L/XL, Blue	1000001840	1000001840				
Underpants with hook-and-loop-tape closure, 2XL/3XL, Blue	1000001841	1000001841				
Colonoscopy pants, long model, S/M, Blue	210818	210818		T0306	Patient protection devices during clinical procedures	
Colonoscopy pants, long model, L/XL, Blue	210819	210819				
Colonoscopy pants, short model, M/L, Blue	210820	210820				
Colonoscopy pants, short model, XL/XXL, Blue	210821	210821				
Gyn. Skirt, OneSize, Blue	1999915463	1999915463				

*expand list
accordingly*

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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	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
Medical devices – Information to be supplied by the manufacturer	EN 20417
Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	ISO 10993-1
Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	ISO 10993-5
Biological evaluation - Part 10: Tests for irritation and skin sensitization	ISO 10993-10
Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	ISO 10993-12

expand list accordingly

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