



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	Diapers and other absorbent hygiene products to absorb urine and liquid feces for incontinent patients. For humans of all sexes and children, adults and the elderly alike.
- 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)

- Notified Body name and identification no. and description of the conformity assessment procedure performed	Not relevant for class 1 products
- 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: Birgitte Hausted Group Concept Manager Signature 	Place and date of issue Aabenraa, DK, 04.10.2023
Abena, Egelund 35, DK-6200 Aabenraa	

Template Responsible: JOHO	Created: JOHO	Approved: ULDA
File: DoC, for ABENA disposable absorbent hygiene products 04.10.2023	Revision/Version: 1.6	Date: 2023-10-04
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EU Declaration of Conformity

Appendix I, List of products

Product Name	EMDN no	EMDN term description	Item no.	Basic UDI-DI
Abena Slip, Premium	T04010102	Shaped incontinence Nappies	1000021279->	57035380AIOBr-001-05001YK
			1000021298	
			1000024469	
			1000024470	
			1999905378	
			1999915798	
Abena Slip Flexi Fit, Premium	T04010102	Shaped incontinence Nappies	1000020859 ->	57035380AIOBr-001-05001YK
			1000020861	
			1000021166	
			1000020863 ->	
			1000020865	
			1000021167	
Abena Pants, Premium	T04010102	Shaped incontinence Nappies	1999905354	57035380AIOBr-001-05001YK
			1999905360	
			1999905375	
			1999905376	
			1000021317->	
			1000021332	
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EU Declaration of Conformity

Product Name	EMDN no	EMDN term description	Item no.	Basic UDI-DI
Abena San, Premium	T04010102	Shaped incontinence Nappies	1000021301-> 1000021316 1000024588	57035380AIOBr-001-05001YK
Abena Maternity pad, Premium	T04010102	Shaped incontinence Nappies	1000022654	57035380AIOBr-001-05001YK
Abena Man, Premium	T04010102	Shaped incontinence Nappies	1000021333-> 1000021336 1999905432 1999905433	57035380AIOBr-001-05001YK
Abena Wing, Premium	T04010103	Incontinence Nappies with integrated fixing system	1999905384-> 1999905397	57035380AIOBr-001-05001YK
Abena Light, Premium	T04010102	Shaped incontinence Nappies	1000021337-> 1000021342 1999905382 1999905383	57035380AIOBr-001-05001YK
Abena Let	T04010101	Rectangular incontinence Nappies	1000021343-> 1000021345 1999905441	57035380AIOBr-001-05001YK
Delta San	T04010102	Shaped incontinence Nappies	1000021661 1000021662 308836	57035380AIOBr-001-05001YK

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EU Declaration of Conformity

Product Name	EMDN no	EMDN term description	Item no.	Basic UDI-DI
Delta Form	T04010102	Shaped incontinence Nappies	308838	57035380AIOBr-001-05001YK
			308839	
			308840	
			100021663	
			308810	
			308811	
			308851	
			308852	
			308862	
			308872	
Abena Abri-Form Comfort	T04010102	Shaped incontinence Nappies	308853	57035380AIOBr-001-05001YK
			308863	
			308873	
			308875	
			4155	
			4160 ->	
			4162	
			4165->	
			4167	
			4169	

expand list accordingly

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EU Declaration of Conformity

Appendix II, List of applicable standards used

Standard title	No. and year
Vocabulary (not relevant, use EDANA instead)	ISO 9949-1:1993
Whole Product Testing "Rothwell"	ISO 11948-1 :1996 (2018)
Biocompatibility	ISO 10993-1 :2018
Quality Management Systems for Medical Devices	ISO 13485:2016
Medical Device Labelling	ISO 15223-1:2016
Risk Management for Medical Devices	ISO 14791:2019
German GKV-MDS Prüfmethode Nr. 12/2015 "MOS-HI"	No.12/2015

expand list accordingly

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