



## 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: <b>Birgitte Hausted</b> Group Concept Manager Signature 	Place and date of issue Aabenraa, DK, 15.04.2024
Abena, Egelund 35, DK-6200 Aabenraa	

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File: DoC, for ABENA disposable absorbent hygiene products april 2024	Revision/Version: 1.6	Date: 2024-04-15
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### 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	
Abena Slip Flexi Fit, Premium	T04010102	Shaped incontinence Nappies	1999915798	57035380AIOBr-001-05001YK
			1000020859 →	
			1000020861	
			1000021166	
			1000020863 →	
Abena Pants, Premium	T04010102	Shaped incontinence Nappies	1000020865	57035380AIOBr-001-05001YK
			1000021167	
			1999905354	
			1999905360	
			1999905375	
			1999905376	
			1000021317 →	
			1000021332	

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Product Name	EMDN no	EMDN term description	Item no.	Basic UDI-DI
Abena San, Premium	T04010102	Shaped incontinence Nappies	1000021301 →	57035380AIOBr-001-05001YK
			1000021316	
			1000024588	
Abena Maternity pad, Premium	T04010102	Shaped incontinence Nappies	1000022654	57035380AIOBr-001-05001YK
			1000021333 →	
Abena Man, Premium	T04010102	Shaped incontinence Nappies	1000021336	57035380AIOBr-001-05001YK
			1999905432	
			1999905433	
Abena Wing, Premium	T04010103	Incontinence Nappies with integrated fixing system	1999905384 →	57035380AIOBr-001-05001YK
			1999905397	
			1000021337 →	
Abena Light, Premium	T04010102	Shaped incontinence Nappies	1000021342	57035380AIOBr-001-05001YK
			1999905382	
			1999905383	
Abena Let	T04010101	Rectangular incontinence Nappies	1000021343 →	57035380AIOBr-001-05001YK
			1000021345	
			1999905441	
Delta San	T04010102	Shaped incontinence Nappies	1000021661	57035380AIOBr-001-05001YK
			1000021662	
			308836	
			308838	
			308839	

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Product Name	EMDN no	EMDN term description	Item no.	Basic UDI-DI
Delta Slip	T04010102	Shaped incontinence Nappies	308840	57035380AIOBr-001-05001YK
			1000025231	
			1000025232	
			1000025234	
			1000025235	
			1000025237	
			1000025238	
			1000025240	
			1000025241	
			1999919305 →	
1999919311				
Abena Slip Basic	T04010102	Shaped incontinence Nappies	1000025107 → 1000025114	57035380AIOBr-001-05001YK

*expand list accordingly*

## 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

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## EU Declaration of Conformity

Standard title	No. and year
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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