



EU Declaration of Conformity for
Disposable absorbent hygiene Products
for the Relief of Incontinence Symptoms

Legal Manufacturer

- Name	ABENA A/S	www.abena.com
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- 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)

- Basic UDI-DI	57035380AIOBr-00I-05001YK Please see appendix I: List of products
- Product/trade name(s) and/or product code(s) (REF)/and or catalogue number	Abena Incontinence products listed in appendix I
- 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.
- Risk classification	Class I non sterile, as of Annex VIII, rule 1.
EMDN codes	T04 – Incontinence Devices T0401 – Urine Absorbing Devices T04010101 – Rectangular Incontinence Nappies (Abena Let) T04010102 – Shaped Incontinence Nappies (Abena Slip/Form, Abena Pants/Flex, Abena Light and the corresponding Abri series) T04010103 – Incontinence Nappies with Integrated Fixing System Not T04010104 - Net Pants (corresponding to Abri Fix series) Not T04010199 - Incontinence Nappies - Other (all others)

Other information (if applicable)

- Applied harmonized standards and technical specifications	ISO 9949 Vocabulary (not relevant, use EDANA instead) ISO 11948-1 "Rothwell" Whole Product Testing ISO 10993-1 Biocompatibility ISO 13485 Quality Management Systems for Medical Devices ISO 14971 Risk Management for Medical Devices ISO 15223 Medical Device Labelling ISO 20417 Information supplied by the manufacturer German GKV-MDS Prüfmethode Nr. 12/2015 "MDS-Hi"
- Notified Body name and identification no. and description of the conformity assessment procedure performed	Not relevant for class 1 products

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 EU legislations mentioned under "additional information".

ABENA A/S including ABENA International A/S.

This Declaration of Conformity is issued under the sole responsibility of the above mentioned manufacturer.



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Name and Function:

Birgitte Hausted

Group Concept Manager

Abena Global Supply

Signature

A handwritten signature in black ink, appearing to be "B. Hausted", written over the printed name and title.

Place and date of issue

Aabenraa, DK, 16.02.2022

Abena, Egelund 35, DK-6200 Aabenraa



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Appendix I, List of products

Product name	Item no.	Basic UDI-DI	Intended Purpose
Abena Slip	1000021279 -> 1000021298 1999905378	57035380AIOBr-00I- 05001YK	Disposable single-use absorbent hygiene products to absorb urine and liquid feces for patients with incontinence symptoms. For humans of all sexes and ages.
Abena Slip Flexi Fit	1000020859 -> 1000020861 1000021166 1000020863 -> 1000020865 1000021167	57035380AIOBr-00I- 05001YK	Disposable single-use absorbent hygiene products to absorb urine and liquid feces for patients with incontinence symptoms. For humans of all sexes and ages.
Abena Pants	1999905354 1999905360 1999905375 1999905376 1000021317-> 1000021332	57035380AIOBr-00I- 05001YK	Disposable single-use absorbent hygiene products to absorb urine and liquid feces for patients with incontinence symptoms. For humans of all sexes and ages.
Abena San	1000021301-> 1000021316	57035380AIOBr-00I- 05001YK	Disposable single-use absorbent hygiene products to absorb urine and liquid feces for patients with incontinence symptoms. For humans of all sexes and ages.
Abena Maternity pad	1000022654	57035380AIOBr-00I- 05001YK	Disposable single-use absorbent hygiene products to absorb urine and liquid feces for patients with incontinence symptoms. For humans of all sexes and ages.
Abena Man	1000021333-> 1000021336 1999905432 1999905433	57035380AIOBr-00I- 05001YK	Disposable single-use absorbent hygiene products to absorb urine and liquid feces for patients with incontinence symptoms. For humans of all sexes and ages.
Abena Wing	1999905384-> 1999905397	57035380AIOBr-00I- 05001YK	Disposable single-use absorbent hygiene products to absorb urine and liquid feces for patients with incontinence symptoms. For humans of all sexes and ages.
Abena Light	1000021337-> 1000021342 1999905382 1999905383	57035380AIOBr-00I- 05001YK	Disposable single-use absorbent hygiene products to absorb urine and liquid feces for patients with incontinence symptoms. For humans of all sexes and ages.
Abena Let	1000021343-> 1000021345 1999905441	57035380AIOBr-00I- 05001YK	Disposable single-use absorbent hygiene products to absorb urine and liquid feces for patients with incontinence symptoms. For humans of all sexes and ages.



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Product name	Item no.	Basic UDI-DI	Intended Purpose
Delta San	1000021661	57035380AIOBr-00I-05001YK	Disposable single-use absorbent hygiene products to absorb urine and liquid feces for patients with incontinence symptoms. For humans of all sexes and ages.
	1000021662		
	308836		
	308838		
	308839		
	308840		
Delta Form	1000021663	57035380AIOBr-00I-05001YK	Disposable single-use absorbent hygiene products to absorb urine and liquid feces for patients with incontinence symptoms. For humans of all sexes and ages.
	308810		
	308811		
	308851		
	308852		
	308862		
	308872		
	308853		
	308863		
	308873		
	308875		

expand list accordingly