



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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- Single Registration Number (SRN)	DK-MF-000002482	

**Medical Device(s)**

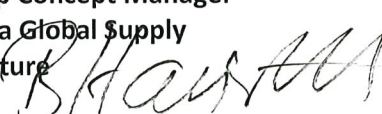
- Basic UDI-DI	57035380AIOBr-001-05001YK Please see appendix I: List of products
- Product/trade name(s) and/or product code(s) (REF)/and or catalogue number	Abena Incontinence products listed in appendix I
- Intended Purpose	Diapers and other absorbent hygiene products to absorb urine and liquid feces 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.

**Other information (if applicable)**

- Applied harmonized standards and technical specifications	ISO 9949-1:1993 Vocabulary (not relevant, use EDANA instead) ISO 11948-1 :1996 (2018) Whole Product Testing "Rothwell" ISO 10993-1 :2018 Biocompatibility ISO 13485:2016 Quality Management Systems for Medical Devices ISO 15223-1:2016 Medical Device Labelling ISO 14791:2019 Risk Management for Medical Devices 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 mention 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".

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

Name and Function: <b>Birgitte Hausted</b> <b>Group Concept Manager</b> <b>Abena Global Supply</b> Signature  ----- Abena, Egelund 35, DK-6200 Aabenraa	<b>Place and date of issue</b> Aabenraa, DK, 04.05.2021
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Appendix I, List of products

Product name	Product type	UDI-DI	Intended Purpose
Abena Abri	Form	57035380AIOBr-00I-05001YK	Pads and similar absorbent hygiene products to absorb urine and liquid feces of incontinence patience
Abena	Slip	57035380AIOBr-00I-05001YK	Pads and similar absorbent hygiene products to absorb urine and liquid feces of incontinence patience
Abena Abri	Flex	57035380AIOBr-00I-05001YK	Pads and similar absorbent hygiene products to absorb urine and liquid feces of incontinence patience
Abena	Pants	57035380AIOBr-00I-05001YK	Pads and similar absorbent hygiene products to absorb urine and liquid feces of incontinence patience
Abena Abri	San	57035380AIOBr-00I-05001YK	Pads and similar absorbent hygiene products to absorb urine and liquid feces of incontinence patience
Abena	Maternity pad	57035380AIOBr-00I-05001YK	Pads and similar absorbent hygiene products to absorb urine and liquid feces of incontinence patience
Abena	Man	57035380AIOBr-00I-05001YK	Pads and similar absorbent hygiene products to absorb urine and liquid feces of incontinence patience
Abena Abri	Man	57035380AIOBr-00I-05001YK	Pads and similar absorbent hygiene products to absorb urine and liquid feces of incontinence patience
Abena Abri	Wing	57035380AIOBr-00I-05001YK	Pads and similar absorbent hygiene products to absorb urine and liquid feces of incontinence patience
Abena	Light	57035380AIOBr-00I-05001YK	Pads and similar absorbent hygiene products to absorb urine and liquid feces of incontinence patience
Abena Abri	Let	57035380AIOBr-00I-05001YK	Pads and similar absorbent hygiene products to absorb urine and liquid feces of incontinence patience
Abena Abri	Light	57035380AIOBr-00I-05001YK	Pads and similar absorbent hygiene products to absorb urine and liquid feces of incontinence patience
Delta	Form	57035380AIOBr-00I-05001YK	Pads and similar absorbent hygiene products to absorb urine and liquid feces of incontinence patience
Delta	San	57035380AIOBr-00I-05001YK	Pads and similar absorbent hygiene products to absorb urine and liquid feces of incontinence patience

*expand list accordingly*

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