



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

**Legal Manufacturer**

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- 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.

**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  13/12-21	<b>Place and date of issue</b> Aabenraa, DK, 13.12.2021
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.

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Product name	Item no.	Basic UDI-DI	Intended Purpose
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
Delta San	1000021661 1000021662 308836 308838 308839 308840	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.
Delta Form	1000021663 308810 308811 308851 308852 308862 308872 308853 308863 308873 308875	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.

*expand list accordingly*

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