



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)**

- Intended Purpose	Abri-Bag Vomit: Bag with absorbent pad for capturing vomitus  Abri-Bag Urinal: Bag with absorbent pad for capturing urine  Abri-Bag: bedpan/commode: Bag with absorbent pad for incontinence use  Abri-bag absorbent pad: Absorbent pad for absorbing body fluids
- 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)**

- Common Specifications used for compliance	A set of technical and/or clinical requirement, other than a standard, that provides a means of complying with the legal obligations applicable
- Notified Body name and identification no. and description of the conformity assessment procedure performed	N/A for class I
- Standards used to assure compliance	ISO 9949-1:1993 Vocabulary (not relevant, use EDANA instead) ISO 13485:2016 Quality Management Systems for Medical Devices ISO 15223-1:2016 Medical Device Labelling ISO 14971:2019 Risk Management for Medical Devices EN 1041:2008+A12013

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 legislations mentioned "Compliance to other legislations".

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

Name and Function:

**Birgitte Hausted**

**Group Concept Manager**

**ABENA Global Supply**

Signature

**Place and date of issue**

Aabenraa, DK, 03.01.2023

Abena, Egelund 35, DK-6200 Aabenraa

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Appendix I, List of products

Product Name	EMDN no	EMDN term description	Item no.	Basic UDI-DI
<b>ABENA Abri-Bag, Absorbent Bedpan Liner</b>	A060303	URINE COLLECTION SYSTEMS AND BAGS, SINGLE-USE	1000005111	57035380StLiB-00I-060018D
<b>ABENA Abri-Bag, Absorbent Commode Liner</b>	A060303	URINE COLLECTION SYSTEMS AND BAGS, SINGLE-USE	1000005113	57035380StLiB-00I-060018D
<b>ABENA Abri-Bag, Absorbent Commode Liner, Sample pack</b>	A060303	URINE COLLECTION SYSTEMS AND BAGS, SINGLE-USE	1000005114	57035380StLiB-00I-060018D
<b>ABENA Abri-Bag, Absorbent Male Urinal</b>	A060303	URINE COLLECTION SYSTEMS AND BAGS, SINGLE-USE	1000010878	57035380DiBot-00I-060019A
<b>ABENA Abri-Bag, Absorbent Vomit Bag</b>	A0603	FLUIDS COLLECTION BAGS AND SYSTEMS	1000010879	57035380SbagS-00I-06001JU
<b>ABENA Abri-Bag, Super Absorbent Pad</b>	A060303	URINE COLLECTION SYSTEMS AND BAGS, SINGLE-USE	1000011839	57035380AbInI-00I-06001TF

*expand list accordingly*

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