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

Legal Manufacturer

- Name - Address - Phone / fax / email / webpage	ABENA A/S Egelund 35 DK-6200 Aabenraa Denmark	www.abena.com Phone: +45 7431 1818 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.

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:
Birgitte Hausted
Group Concept Manager
Abena Global Supply
Signature

Place and date of issue
Aabenraa, DK, 01.06.2021

Abena, Egelund 35, DK-6200 Aabenraa

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

Appendix I, List of products

Product name	Product type	Basic 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