



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

Legal Manufacturer

- Name	ABENA A/S	www.abena.com
- Address	Egelund 35	Phone: +45 7431 1818
- 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.