EU Declaration of Conformity for Fixation Pants for incontinence products

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	57035380AbFiL-00I-06002PM Please see appendix I: List of products
- Product/trade name(s) and product code(s) (REF)/and or catalogue number	Abena Abri Fixation products listed in appendix I
- Intended Purpose	Reusable (washable) textile fixation devices for fixating of i.e. a bandage or a pad, worn as a normal underwear pants for alleviation of continence diseases or handicap.
- Risk classification	Class I according to rule no. 1 in MDR annex VIII

Other information (if applicable)

- Applied harmonized standards and technical specifications	ISO 13934 – Textile Tensile Strength ISO 2060 – Textiles – Determination of density Oeko-Tex 100 – Testing of textile ecology ISO 10993-1 | 10995-5 Biological Evaluation ISO 13485 Quality Management Systems for Medical Devices ISO 15223 Medical Device Symbols ISO 14791 Risk Management for Medical Devices
- Notified Body name and identification no. and description of the conformity assessment procedure performed	N/A

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:
Krisztina Hajdu Lindhardt
Senior Product Manager Incontinence
Abena Global Supply
Signature

Place and date of issue
Aabenraa, DK, 28.06.2021

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 Abri-Fix One	4255	57035380AbFiL-00I-06002PM	Reusable (washable) textile fixation devices for fixating of i.e. a bandage or a pad, worn as a normal underwear pants for alleviation of continence diseases or handicap.
Abena Abri-Fix One Super	4256	57035380AbFiL-00I-06002PM	Reusable (washable) textile fixation devices for fixating of i.e. a bandage or a pad, worn as a normal underwear pants for alleviation of continence diseases or handicap.
Abena Abri-Fix Net (S-XXL)	4249-4253 9249-9252, 9256	57035380AbFiL-00I-06002PM	Reusable (washable) textile fixation devices for fixating of i.e. a bandage or a pad, worn as a normal underwear pants for alleviation of continence diseases or handicap.
Abena Abri-Fix Pants Super (S-6XL)	90691, 90692, 90693, 90694, 90695, 90696, 90697, 90698, 90699	57035380AbFiL-00I-06002PM	Reusable (washable) textile fixation devices for fixating of i.e. a bandage or a pad, worn as a normal underwear pants for alleviation of continence diseases or handicap.
Abena Abri-Fix Net Eco (M-L-XL)	1000002726, 100002727 1000002728	57035380AbFiL-00I-06002PM	Reusable (washable) textile fixation devices for fixating of i.e. a bandage or a pad, worn as a normal underwear pants for alleviation of continence diseases or handicap.