



## EU Declaration of Conformity

### Legal Manufacturer

- Name	ABENA A/S	www.abena.com
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- 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	57035380PShPa-001-05001VK
- Product/trade name(s) and/or product code(s) (REF)/and or catalogue number	<b>Incontinence pads:</b> facelle diskret Men Level 1 facelle diskret Men Level 2 facelle diskret Men Level 3 facelle diskret Vorlagen, Maxi facelle diskret Vorlagen, Super
- Other ref. allowing identification (e.g. UDI-DI)	Please see 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, as of Annex VIII, rule 1.

### Other information (if applicable)

- Common Specifications used for compliance	-
- Notified Body name and identification no. and description of the conformity assessment procedure performed	Not relevant for class I products
- Additional information	-
- Standards used to assure compliance	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 15223 Medical Device Labelling ISO 20417 Information supplied by the manufacturer ISO 14971 Risk Management for Medical Devices German GKV-MDS Prüfmethode Nr. 12/2015 "MDS-Hi"

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".

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

Name and Function: <b>Charlotte Lock Behrendtz, Business Developer Compliance</b>	<b>Place and date of issue</b> Aabenraa, DK, 24.06.2021
Signature 	

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Abena, Egelund 35, DK-6200 Aabenraa

### Appendix I, List of products

Product Name	Item no.	UDI-DI	Intended Purpose
Incontinence pads, facelle diskret, MEN, Level 1, white	1000019077	57035380PShPa-00I-05001VK	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.
Incontinence pads, facelle diskret, MEN, Level 2, white	1000019078	57035380PShPa-00I-05001VK	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.
Incontinence pads, facelle diskret, MEN, Level 3, white	1000019079	57035380PShPa-00I-05001VK	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.
Vorlagen, facelle diskret, Maxi, white	1000020239	57035380PShPa-00I-05001VK	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.
Vorlagen, facelle diskret, Super, white	1000020238	57035380PShPa-00I-05001VK	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.

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