



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

**Legal Manufacturer**

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- Single Registration Number (SRN)	DK-MF-000002482	

**Medical Device(s)**

- Basic UDI-DI	57035380BSamB-001-050012L Please see appendix I: List of products
- Product/trade name(s) and/or product code(s) (REF)/and or catalogue number	Abena Bambo Nature children diapers listed in appendix I
- Intended Purpose	Disposable absorbent hygiene products to absorb urine and liquid feces for incontinent patients. For children of both sexes.
- Risk classification	Class I non sterile, as of Annex VIII, rule 1.
- EMDN codes	T04 - Incontinence Devices T0401 - Urine Absorbing Devices <b>T04010102</b> - Shaped Incontinence Nappies (All Abena Bambo Nature children diapers in appendix 1)

**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 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"
- 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".

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

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Name and Function:  
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**Group Concept Manager**  
**Abena Global Supply**

Signature

**Place and date of issue**

Aabenraa, DK, 21.10.2024

Abena, Egelund 35, DK-6200 Aabenraa

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Appendix I, List of products

Product name	Item no.	Basic UDI-DI	Intended Purpose
Bambo Nature Pants	310138, 310139, 1000019258, 1000019259, 1000021518, 1000021519, 1000021355, 1000021356, 1000023781, 1000026341	57035380BSamB-00I- 050012L	Disposable absorbent hygiene products to absorb urine and liquid feces for incontinent patients. For children of both sexes.
Bambo Nature Open diaper	310135, 310136, 310145, 310146, 1000019255, 1000019256, 1000019265, 1000019266, 1000021515, 1000021516, 1000020793, 1000025482	57035380BSamB-00I- 050012L	Disposable absorbent hygiene products to absorb urine and liquid feces for incontinent patients. For children of both sexes.
Bambo Dreamy Night Pants	1000018874-1000018877 1000024824, 1000024825	57035380BSamB-00I- 050012L	Disposable absorbent hygiene products to absorb urine and liquid feces for incontinent patients. For children of both sexes.

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