



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

**Legal Manufacturer**

|                                    |                             |                                            |
|------------------------------------|-----------------------------|--------------------------------------------|
| - Name                             | ABENA A/S                   | www.abena.com                              |
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| - Single Registration Number (SRN) | DK-MF-000002482             |                                            |

**Medical Device(s)**

|                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| - Basic UDI-DI                                                               | 57035380AIOBr-00I-05001YK<br>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<br>T0401 – Urine Absorbing Devices<br><b>T04010101</b> – Rectangular Incontinence Nappies (Abena Let)<br><b>T04010102</b> – Shaped Incontinence Nappies (Abena Slip/Form, Abena Pants/Flex, Abena Light and the corresponding Abri series)<br><b>T04010103</b> – Incontinence Nappies with Integrated Fixing System<br>Not T04010104 - Net Pants (corresponding to Abri Fix series)<br>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)<br>ISO 11948-1 "Rothwell" Whole Product Testing<br>ISO 10993-1 Biocompatibility<br>ISO 13485 Quality Management Systems for Medical Devices<br>ISO 14971 Risk Management for Medical Devices<br>ISO 15223 Medical Device Labelling<br>ISO 20417 Information supplied by the manufacturer<br>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.