# EU Declaration of Conformity

**Legal Manufacturer**

| | | |
|---|---|---|
| - Name<br>- Address<br>- Phone / fax / email / webpage | ABENA A/S<br>Egelund 35<br>DK-6200 Aabenraa<br>Denmark | www.ABENA.com<br>Phone: +45 7431 1818<br>Fax: +45 7462 9737<br>Mail: info@ABENA.com |
| - Single Registration Number (SRN) | DK-MF-000002482 | |

**Medical Device(s)**

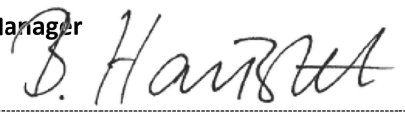
| | |
|---|---|
| - Intended Purpose | Diapers and other absorbent hygiene products to absorb urine and liquid feces for incontinent patients. For humans of all sexes and children, adults and the elderly alike. |
| - Product/trade name(s) and product code(s) (REF)/and or catalogue number | Please see appendix I |
| - Basic UDI-DI | Please see appendix I |
| - Other ref. allowing identification (e.g. UDI-DI) | Please see appendix I |
| - EMDN (no. and term) | Please see appendix I |
| - Risk classification | Class I according to rule no. 1, MDR annex VIII |
| - Conformity route | MDR annex II and III |

**Other information (if applicable)**

| | |
|---|---|
| - Notified Body name and identification no. and description of the conformity assessment procedure performed | Not relevant for class 1 products |
| - Standards used to assure compliance | Please see appendix II |

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 legislations mentioned "Compliance to other legislations".
This Declaration of Conformity is issued under the sole responsibility of the above mentioned manufacturer.

Name and Function:
**Birgitte Hausted**
**Group Concept Manager**
**Signature**



**Place and date of issue**
Aabenraa, DK, 13.08.25

ABENA, Egelund 35, DK-6200 Aabenraa

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## Appendix I, List of products

| Product Name | EMDN no | EMDN term description | Item no. | Basic UDI-DI |
|---|---|---|---|---|
| ABENA Slip, Premium | T04010102 | Shaped incontinence Nappies | 1000021279<br>1000021280<br><br>1000021281<br>1000021282<br><br>1000021283<br>1000021284<br>1000021285<br>1000021286<br>1000021287<br>1000031056<br><br>1000021288<br>1000021289<br>1000021290<br>1000021291<br>1000021292<br>1000031057<br><br>1000021293<br>1000021294<br>1000021295<br>1000021296<br>1000021297 | 57035380AIOBr-00I-05001YK |

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| Product Name | EMDN no | EMDN term description | Item no. | Basic UDI-DI |
|---|---|---|---|---|
| | | | 1000021298<br><br>1000024469<br>1000024470<br><br>1999905378<br>1999915798 | |
| ABENA Slip<br>Flexi Fit, Premium | T04010102 | Shaped incontinence Nappies | 1000020859<br>1000020860<br>1000020861<br><br>1000021166<br><br>1000020863<br>1000020864<br>1000020865<br><br>1000021167 | 57035380AIOBr-00I-05001YK |
| ABENA Wing, Premium | T04010103 | Incontinence Nappies with integrated fixing system | 1999905384<br>1999905385<br>1999905386<br>1999905387<br>1999905388<br>1999905389<br>1999905390<br>1999905391<br>1999905392 | 57035380AIOBr-00I-05001YK |

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| Product Name | EMDN no | EMDN term description | Item no. | Basic UDI-DI |
|---|---|---|---|---|
| | | | 1999905393<br>1999905394<br>1999905395<br>1999905396<br>1999905397 | |
| ABENA Maternity pad, Premium | T04010102 | Shaped incontinence Nappies | 1000022654 | 57035380AIOBr-00I-05001YK |
| ABENA Pants, Premium | T04010102 | Shaped incontinence Nappies | 1999905354<br>1999905360<br>1999905375<br>1999905376<br><br>1000021317<br>1000021318<br>1000021319<br>1000021320<br>1000021321<br>1000021322<br>1000021323<br>1000021324<br>1000021325<br>1000021326<br>1000021327<br>1000021328<br>1000021329<br>1000021330<br>1000021331 | 57035380AIOBr-00I-05001YK |

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| Product Name | EMDN no | EMDN term description | Item no. | Basic UDI-DI |
|---|---|---|---|---|
| | | | 1000021332 | |
| ABENA Let | T04010101 | Rectangular incontinence Nappies | 1000021343<br>1000021344<br>1000021345<br><br>1999905441 | 57035380AIOBr-00I-05001YK |
| ABENA San, Premium | T04010102 | Shaped incontinence Nappies | 1000021301<br>1000021302<br>1000021303<br>1000021304<br>1000021305<br>1000021306<br>1000021307<br>1000021308<br>1000021309<br>1000021310<br>1000021311<br>1000021312<br>1000021313<br>1000021314<br>1000021315<br>1000021316<br><br>1000024588 | 57035380AIOBr-00I-05001YK |

# EU Declaration of Conformity

| Product Name | EMDN no | EMDN term description | Item no. | Basic UDI-DI |
|---|---|---|---|---|
| ABENA Light, Premium | T04010102 | Shaped incontinence Nappies | 1000021337<br>1000021338<br>1000021339<br>1000021340<br>1000021341<br>1000021342<br><br>1999905382<br>1999905383 | 57035380AIOBr-00I-05001YK |
| ABENA San Basic | T04010102 | Shaped incontinence Nappies | 1000027520<br>1000027521<br>1000027522<br>1000027523<br>1000027524<br>1000027525 | 57035380AIOBr-00I-05001YK |
| Delta Slip | T04010102 | Shaped incontinence Nappies | 1000025231<br>1000025232<br><br>1000025234<br>1000025235<br><br>1000025237<br>1000025238<br><br>1000025240<br>1000025241<br><br>1000029455 | 57035380AIOBr-00I-05001YK |

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| Product Name | EMDN no | EMDN term description | Item no. | Basic UDI-DI |
|---|---|---|---|---|
| | | | 1000029456<br><br>1999919305<br>1999919306<br>1999919307<br>1999919308<br>1999919309<br>1999919310<br>1999919311 | |
| ABENA Man, Premium | T04010102 | Shaped incontinence Nappies | 1000021333<br>1000021334<br>1000021335<br>1000021336<br><br>1999905432<br>1999905433 | 57035380AIOBr-00I-05001YK |
| Delta San | T04010102 | Shaped incontinence Nappies | 1000021661<br>1000021662<br><br>308836<br>308838<br>308839<br>308840 | 57035380AIOBr-00I-05001YK |
| Delta Form | T04010102 | Shaped incontinence Nappies | 1000021663<br><br>308810 | 57035380AIOBr-00I-05001YK |

# EU Declaration of Conformity

| Product Name | EMDN no | EMDN term description | Item no. | Basic UDI-DI |
|---|---|---|---|---|
| | | | 308811<br><br>308851<br>308852<br>308853<br>308862<br>308863<br>308872<br>308873<br>308875 | |
| ABENA Slip Basic | T04010102 | Shaped incontinence Nappies | 1000025107<br>1000025108<br>1000025109<br>1000025110<br>1000025111<br>1000025112<br>1000025113<br>1000025114 | 57035380AIOBr-00I-05001YK |
| Abri-Form Comfort | T04010102 | Shaped incontinence Nappies | 4155<br>4160<br>4161<br>4162<br>4165<br>4166<br>4167<br>4169 | 57035380AIOBr-00I-05001YK |

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| Product Name | EMDN no | EMDN term description | Item no. | Basic UDI-DI |
|---|---|---|---|---|
| ABENA Pants Basic | T04010102 | Shaped incontinence Nappies | 1000031065<br>1000031066<br>1000031067<br>1000031068<br>1000031069<br>1000031070 | 57035380AIOBr-00I-05001YK |

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## Appendix II, List of applicable standards used

| **Standard title** | **No. and year** |
|---|---|
| Vocabulary (not relevant, use EDANA instead) | ISO 9949-1:1993 |
| Whole Product Testing "Rothwell" | ISO 11948-1 :1996 (2018) |
| Biocompatibility | ISO 10993-1 :2018 |
| Quality Management Systems for Medical Devices | ISO 13485:2016 |
| Medical Device Labelling | ISO 15223-1:2016 |
| Risk Management for Medical Devices | ISO 14791:2019 |
| German GKV-MDS PrUfmethode Nr. 12/2015 "MOS-Hi" | No.12/2015 |