



## EU Declaration of Conformity

### Legal Manufacturer

|                                    |                             |                                            |
|------------------------------------|-----------------------------|--------------------------------------------|
| - Name                             | ABENA A/S                   | www.abena.com                              |
| - Address                          | Egelund 35                  | Phone: +45 7431 1818                       |
| - Phone / fax / email / webpage    | DK-6200 Aabenraa<br>Denmark | 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 mentioned 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:<br><b>Birgitte Hausted</b><br>Group Concept Manager<br>Signature  | Place and date of issue<br>Aabenraa, DK, 04.10.2023 |
| Abena, Egelund 35, DK-6200 Aabenraa                                                                                                                                     |                                                     |

|                                                                          |                       |                  |
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| File: DoC, for ABENA disposable absorbent hygiene products<br>04.10.2023 | Revision/Version: 1.6 | Date: 2023-10-04 |
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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->  | 57035380AIOBr-001-05001YK |
|                                                                      |                       |                             | 1000021298    |                           |
|                                                                      |                       |                             | 1000024469    |                           |
|                                                                      |                       |                             | 1000024470    |                           |
|                                                                      |                       |                             | 1999905378    |                           |
|                                                                      |                       |                             | 1999915798    |                           |
| Abena Slip<br>Flexi Fit, Premium                                     | T04010102             | Shaped incontinence Nappies | 1000020859 -> | 57035380AIOBr-001-05001YK |
|                                                                      |                       |                             | 1000020861    |                           |
|                                                                      |                       |                             | 1000021166    |                           |
|                                                                      |                       |                             | 1000020863 -> |                           |
|                                                                      |                       |                             | 1000020865    |                           |
|                                                                      |                       |                             | 1000021167    |                           |
| Abena Pants, Premium                                                 | T04010102             | Shaped incontinence Nappies | 1999905354    | 57035380AIOBr-001-05001YK |
|                                                                      |                       |                             | 1999905360    |                           |
|                                                                      |                       |                             | 1999905375    |                           |
|                                                                      |                       |                             | 1999905376    |                           |
|                                                                      |                       |                             | 1000021317->  |                           |
|                                                                      |                       |                             | 1000021332    |                           |
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| Product Name                 | EMDN no   | EMDN term description                              | Item no.                                               | Basic UDI-DI              |
|------------------------------|-----------|----------------------------------------------------|--------------------------------------------------------|---------------------------|
| Abena San, Premium           | T04010102 | Shaped incontinence Nappies                        | 1000021301-><br>1000021316<br>1000024588               | 57035380AIOBr-001-05001YK |
| Abena Maternity pad, Premium | T04010102 | Shaped incontinence Nappies                        | 1000022654                                             | 57035380AIOBr-001-05001YK |
| Abena Man, Premium           | T04010102 | Shaped incontinence Nappies                        | 1000021333-><br>1000021336<br>1999905432<br>1999905433 | 57035380AIOBr-001-05001YK |
| Abena Wing, Premium          | T04010103 | Incontinence Nappies with integrated fixing system | 1999905384-><br>1999905397                             | 57035380AIOBr-001-05001YK |
| Abena Light, Premium         | T04010102 | Shaped incontinence Nappies                        | 1000021337-><br>1000021342<br>1999905382<br>1999905383 | 57035380AIOBr-001-05001YK |
| Abena Let                    | T04010101 | Rectangular incontinence Nappies                   | 1000021343-><br>1000021345<br>1999905441               | 57035380AIOBr-001-05001YK |
| Delta San                    | T04010102 | Shaped incontinence Nappies                        | 1000021661<br>1000021662<br>308836                     | 57035380AIOBr-001-05001YK |

|                                                                       |                       |                  |
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| Product Name            | EMDN no   | EMDN term description       | Item no.  | Basic UDI-DI              |
|-------------------------|-----------|-----------------------------|-----------|---------------------------|
| Delta Form              | T04010102 | Shaped incontinence Nappies | 308838    | 57035380AIOBr-001-05001YK |
|                         |           |                             | 308839    |                           |
|                         |           |                             | 308840    |                           |
|                         |           |                             | 100021663 |                           |
|                         |           |                             | 308810    |                           |
|                         |           |                             | 308811    |                           |
|                         |           |                             | 308851    |                           |
|                         |           |                             | 308852    |                           |
|                         |           |                             | 308862    |                           |
|                         |           |                             | 308872    |                           |
| Abena Abri-Form Comfort | T04010102 | Shaped incontinence Nappies | 308853    | 57035380AIOBr-001-05001YK |
|                         |           |                             | 308863    |                           |
|                         |           |                             | 308873    |                           |
|                         |           |                             | 308875    |                           |
|                         |           |                             | 4155      |                           |
|                         |           |                             | 4160 ->   |                           |
|                         |           |                             | 4162      |                           |
|                         |           |                             | 4165->    |                           |
|                         |           |                             | 4167      |                           |
|                         |           |                             | 4169      |                           |

expand list accordingly

|                                                                       |                       |                  |
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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 Prüfmethode Nr. 12/2015 "MOS-HI" | No.12/2015               |

expand list accordingly

|                                                                      |                       |                  |
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