EU Declaration of Conformity

Legal Manufacturer

- Name - Address - Phone / fax / email / webpage	ABENA A/S Egelund 35 DK-6200 Aabenraa Denmark	www.ABENA.com Phone: +45 7431 1818 Fax: +45 7462 9737 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

EU Declaration of Conformity

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 1000021280 1000021281 1000021282 1000021283 1000021284 1000021285 1000021286 1000021287 1000031056 1000021288 1000021289 1000021290 1000021291 1000021292 1000031057 1000021293 1000021294 1000021295 1000021296 1000021297	57035380AIOBr-00I-05001YK

EU Declaration of Conformity

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

EU Declaration of Conformity

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

EU Declaration of Conformity

Product Name	EMDN no	EMDN term description	Item no.	Basic UDI-DI
			1000021332	
ABENA Let	T04010101	Rectangular incontinence Nappies	1000021343 1000021344 1000021345 1999905441	57035380AIOBr-00I-05001YK
ABENA San, Premium	T04010102	Shaped incontinence Nappies	1000021301 1000021302 1000021303 1000021304 1000021305 1000021306 1000021307 1000021308 1000021309 1000021310 1000021311 1000021312 1000021313 1000021314 1000021315 1000021316 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 1000021338 1000021339 1000021340 1000021341 1000021342 1999905382 1999905383	57035380AIOBr-00I-05001YK
ABENA San Basic	T04010102	Shaped incontinence Nappies	1000027520 1000027521 1000027522 1000027523 1000027524 1000027525	57035380AIOBr-00I-05001YK
Delta Slip	T04010102	Shaped incontinence Nappies	1000025231 1000025232 1000025234 1000025235 1000025237 1000025238 1000025240 1000025241 1000029455	57035380AIOBr-00I-05001YK

EU Declaration of Conformity

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

EU Declaration of Conformity

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

EU Declaration of Conformity

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

EU Declaration of Conformity

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