



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 Denmark	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 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: Birgitte Hausted Group Concept Manager Signature 	Place and date of issue Aabenraa, DK, 13.08.25
ABENA, Egelund 35, DK-6200 Aabenraa	

Template Responsible: JOHO	Created: JOHO	Approved: ULDA
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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-00I-05001YK
			1000021280	
			1000021281	
			1000021282	
			1000021283	
			1000021284	
			1000021285	
			1000021286	
			1000021287	
			1000031056	
			1000021288	
			1000021289	
			1000021290	
			1000021291	
			1000021292	
			1000031057	
			1000021293	
			1000021294	
			1000021295	
			1000021296	
1000021297				

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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

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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

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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

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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

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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

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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

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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

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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

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Hy-Tec
Hygiene Technologie GmbH
Schillerstrasse 14
42781 Haan

Prüfbericht
Test Report

Nr./No. 6422/1-3

Auftraggeber
By order of

Abena Production A/S
Erik Jessens Vej 37

DK-6200 Aabenraa



Dieser Bericht wurde erstellt am 02.11.2021
This report was carried out on

und überprüft von
and approved by

i.V.Dr. Edgar Herrmann
Laborleiter/ Head of Laboratory

i. V. Dr. Filiz Bley
Stellv. Laborleiterin/Deputy Head of Laboratory

Dieser Bericht enthält/This report contains 65 Seiten/pages (einschließlich Deckblatt/frontal-page) mit/with
Test-Nr./Test No.: MDS/ABL/ISO 53624-53638

Ohne schriftliche Genehmigung der Hy-Tec GmbH dürfen Ergebnisse aus diesem Bericht nicht in Auszügen vervielfältigt werden.
Die Ergebnisse beziehen sich ausschließlich auf die geprüften Proben.

Without permission of Hy-Tec GmbH extracts of this report should not be copied.
The results of this report refer to the tested samples only.
Rückstellmuster werden 2 Monate aufbewahrt.
Retain samples will be kept for 2 months.

Durch die DAkkS Deutsche Akkreditierungsstelle GmbH akkreditiertes Prüflaboratorium.
Die Akkreditierung gilt nur für die in der Urkunde aufgeführten Verfahren.
Der Ausgabestand der verwendeten Normen ist in der Anlage zur Akkreditierungsurkunde zu entnehmen.

The test laboratory is accredited by DAkkS GmbH (German Accreditation Body).
The accreditation only applies to the procedures listed in the certificate.
The applied version of the test methods used can be found in the annex of the accreditation certificate.

Der Firmensitz ist identisch mit dem Prüfort/Company location and test location are identical.

Kundeangaben sind grau unterlegt/Customer-provided information is marked in grey.



Deutsche
Akkreditierungsstelle
D-PL-11015 01-00

Laboratory Test Report Adult Mannequin (WSP 354.0) DIN 13222



General description of tested products

By order of : Abena
 Manufacturer : Abena
 Product name : Abena Pants Premium
 Product size : XL3
 Date of test : 26.10.21
 Name of tester : id
 Int. test No. : 53638
 Code packaging : MD LOT 05.07.21 - 15.33 EXP 07.2026
 PZN : 17457235
 EAN : 5713571001028
 Article No. : 1000021330

Prod. construction :

Number of test samples : 5
 Prod. weight (mean) : 111,7 g
 Prod. weight (min.) : 109,6 g
 Prod. weight (max.) : 112,8 g
 Prod. weight (std.) : 1,41

ABL (mean) : 790 g
 ABL (min.) : 696 g
 ABL (max.) : 883 g
 ABL (SDV) : 72

Remarks :

Absorption before Leakage (WSP 354.1 (11)) DIN 13222

Test No. 53638 dated 26.Okt.21

	1.	2.	3.	4.	5.	mean	s
Product weight [g]	112,5	112,8	112,7	109,6	110,9	111,7	1,4
Wet weight [g]	942,0	864,0	995,8	898,9	807,1	901,6	72,2
ABL [g]	829,50	751,20	883,10	789,30	696,20	789,9	71,6
No. of Mictions [n]	6	5	6	5	5		

