



Declaration of conformity Medical Devices, class I

Legal Manufacturer:	Abena A/S including Abena International Egelund 35 DK 6200 Aabenraa
Conformity assessment procedure	Annex VII of the Medical Devices Directive 93/42/EEC as amended by the Council Directive 2007/47/EEC.
Classification and harmonized standards	Class I non sterile
Product	Abri-Form Premium Abri-Form Premium Junior XS2 43050 Abri-Form Premium XS2 43054 Abri-Form Premium S2 43055 Abri-Form Premium S4 43056 Abri-Form Premium M0 43049 Abri-Form Premium M1 43061 Abri-Form Premium M2 43060 Abri-Form Premium M3 43062 Abri-Form Premium M4 43063 Abri-Form Premium L0 43059 Abri-Form Premium L1 43066 Abri-Form Premium L2 43065 Abri-Form Premium L3 43067 Abri-Form Premium L4 43068 Abri-Form Premium XL2 43069 Abri-Form Premium XL4 43071 Abri-Form Premium (10pcs/pk) Abri-Form Premium M1 4730 Abri-Form Premium M2 4740 Abri-Form Premium L1 4735 Abri-Form Premium L2 4745 Abri-Form Comfort Abri-Form Comfort S2 4155 Abri-Form Comfort M1 4161 Abri-Form Comfort M2 4160 Abri-Form Comfort M3 4162 Abri-Form Comfort L1 4166

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	Abri-Form Comfort L2	4165
	Abri-Form Comfort L3	4167
	Abri-Form Comfort XL2	4169
	Abri-Form Comfort XXL1	300516
	Abri-San Premium	
	Abri-San Premium 1	9253
	Abri-San Premium 1A	9254
	Abri-San Premium 2	9260
	Abri-San Premium 3	9266
	Abri-San Premium 3A	9267
	Abri-San Premium 4	8271
	Abri-San Premium 5	9374
	Abri-San Premium 6	9378
	Abri-San Premium 7	9381
	Abri-San Premium 8	9382
	Abri-San Premium 9	9384
	Abri-San Premium 10	9386
	Abri-San Premium 11	9389
	Abri-San Premium 7 XXL	300514
	Abri-San Premium 11 XXL	300515
	Abri-San Premium Special	300200
	Maternity Pad	
	Maternity Pad Super	1000016571
	Abri-Flex Premium	
	Abri-Flex Premium XS1	1000003163
	Abri-Flex Premium S1	41071
	Abri-Flex Premium S2	41082
	Abri-Flex Premium M0	1000016664
	Abri-Flex Premium M1	41083
	Abri-Flex Premium M2	41084
	Abri-Flex Premium M3	41085
	Abri-Flex Premium L0	100016665
	Abri-Flex Premium L1	41086
	Abri-Flex Premium L2	41087
	Abri-Flex Premium L3	41088
	Abri-Flex Premium XL1	41089
	Abri-Flex Premium XL2	41090
	Abri-Flex Premium XL3	1000016825
	Abri-Flex XXL1	300517
	Abri-Flex Premium Special S/M2	41073
	Abri-Flex Premium Special M/L2	41076
	Abri-Wing Premium	
	Abri-Wing Premium S2	300008

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	Abri-Wing Premium M1	300002
	Abri-Wing Premium M2	300003
	Abri-Wing Premium M3	300004
	Abri-Wing Premium L1	300005
	Abri-Wing Premium L2	300006
	Abri-Wing Premium L3	300007
	Abri-Wing Premium XL2	300010
	Abri-Wing Premium Special M2	300000
	Abri-Wing Premium Special L2	300001
	Abri-Let	
	Abri-Let Super	9041
	Abri-Let Anatomic	300215
	Abri-Let Normal	300216
	Abri-Let Mini	300217
	Abri-Let Maxi	1000001938
	Abri-Man Premium	
	Abri-Man Premium Zero	300740
	Abri-Man Premium Formula 1	41006
	Abri-Man Premium Formula 2	41007
	Abri-Man Premium Special	300744
	Abri-Man Premium Slipguard	207203
	Abri-Light	
	Abri-Light Ultra Mini	41000
	Abri-Light Mini	41001
	Abri-Light Mini Plus	41002
	Abri-Light Normal	41003
	Abri-Light Extra	41004
	Abri-Light Extra Plus	41014
	Abri-Light Super	41005
	Delta-Form	
	Delta-Form S1	308851
	Delta-Form M1	308852
	Delta-Form M2	308862
	Delta-Form M3	308872
	Delta-Form L1	308853
	Delta-Form L2	308863
	Delta-Form L3	308873
	Delta-Form X12	308875
	Delta-Form M1, 25 pcs	308810
	Delta-Form L1, 25 pcs	308811

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Delta-San		
Delta-San No. 6		308836
Delta-San No. 7		308838
Delta-San No. 9		308839
Delta-San No.10		308840
Abena Light		
Abena Light Ultra Mini 0		1000005436
Abena Light Mini 1		1000017155
Abena Light Mini Plus 1A		1000017156
Abena Light Normal 2		1000017157
Abena Light Extra 3		1000017158
Abena Light Extra Plus 3A		1000017159
Abena Light Super 4		1000017160
Abena Light Maxi 4A		1000005437
Abena Man		
Abena Man Formula 0		1000017161
Abena Man Formula 1		1000017162
Abena Man Formula 2		1000017163
Abena Pants		
Abena Pants M0		1000017173
Abena Pants L0		1000017174
Abena Slip		
Abena Slip M0		1000019013
Abena Slip L0		1000019014
Abena Abri-Wing		
Abri-Wing Premium S1		1000009115
Abri-Wing Premium S2		1000009116
Abri-Wing Premium S3		1000009117
Abri-Wing Premium M1		1000009118
Abri-Wing Premium M2		1000009119
Abri-Wing Premium M3		1000009120
Abri-Wing Premium M4		1000009121
Abri-Wing Premium L1		1000009122
Abri-Wing Premium L2		1000009123
Abri-Wing Premium L3		1000009124
Abri-Wing Premium L4		1000009125
Abri-Wing Premium XL1		1000009126
Abri-Wing Premium XL2		1000009127
Abri-Wing Premium XL3		1000009128
Abena Abri-Flex Junior		
Abena Abri-Flex Junior		1000018730

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	Abri-Bag Abri-Bag, Bedpan Liner 1000005111 Abri-Bag, Commode Liner 1000005113 Abri-Bag, Commode Liner, sample 1000005114 Abri-Bag, Urinal 1000010878 Abri-Bag, Vomitus 1000010879 Abri-Bag, Absorbing Pad 1000011839
We, the legal manufacturer hereby declare that the above-mentioned product complies with the European Medical Device Directive 93/42/EEC as amended by the Council Directive 2007/47/EEC and its relevant transposition into all national laws of the member states into which we place the devices.	
Signed in Aabenraa	23-01-2020
Name and authority	Birgitte Hausted Group Concept Manager
Signature	

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