

Manufacturer's EU/UK Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Issuer's name : Medeco B.V.
Issuer's address : Brandpuntlaan Zuid 14
2665 NZ Bleiswijk
The Netherlands

Chamber of commerce # : 23038479

Single registration number : NL-MF-000001628

Object of the declaration : Absorbing Incontinence

Intended purpose :

Product	Intended purpose
Absorin Comfort and Classic	Absorbent products to collect urine and/or faeces for incontinence patients.
Absorin Fix	

Classification : REGULATION (EU) 2017/745 Annex VIII /
UK MDR 2002 (SI 2002 No 618, as amended), see attached
Product list

Conformity assessment : REGULATION (EU) 2017/745 Annex II and Annex III/
Part II of UK MDR 2002 (SI 2002 No 618, as amended),
Annex II excluding section 4

Validity : This declaration of conformity is valid at least during the
lifetime of the products concerned. The declaration will be
updated in case of changes in the product range and after
issuance of a new product or quality system certificate.

Hereby Medeco BV declares that the distributed products as specified in the annexed product list meet the provisions of the Council Regulation 2017/745 of 5 April 2017 on Medical Devices / Medical Device Regulations 2002 (SI 2002 No 618, as amended) and comply to all harmonized standards which are applicable to the products, as published in the Official Journal of the European Union / to meet the UK MDR 2002. Medeco BV further declares that it is exclusively responsible for this declaration of conformity.

Additional information

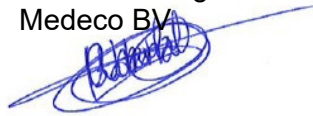
UK Responsible Person : H&R Healthcare Ltd.
UKRP address : 3 Redcliff Road, Melton Park, Melton, Hull, HU14 3RS
United Kingdom

This documentation is supported by the Quality Management System certification based on the harmonized standard EN ISO 13485:2016, Quality Management System Certificate with reference numbers: MD 644507 issued for the 1st time on 20 June 2016, and delivered by BSI. The applied standards for this family of products is maintained in the Technical Dossier.

Bleiswijk, 7 November 2024

Name : W. Baboelal
Function : QA/RA Manager, PRRC
Medeco BV

Signature :



Product list related to DoC MD Class I – Absorbing Incontinence

Ref Nr	Article Description	Class	Rule	BASIC UDI-DI
0720-A	ABSORIN COMFORT SLIP M Day	I	1	18756INCCT0401JS
0730-A	ABSORIN COMFORT SLIP L Day	I	1	18756INCCT0401JS
0805	ABSORIN COMFORT SLIP XXS DAY	I	1	18756INCCT0401JS
0808-A	ABSORIN COMFORT SLIP XS Day	I	1	18756INCCT0401JS
0815-A	ABSORIN COMFORT SLIP S Day/Night	I	1	18756INCCT0401JS
0822-A	ABSORIN COMFORT SLIP M Day/Night	I	1	18756INCCT0401JS
0832-A	ABSORIN COMFORT SLIP L Day/Night	I	1	18756INCCT0401JS
0840-A	ABSORIN COMFORT SLIP XL Day	I	1	18756INCCT0401JS
0842-A	ABSORIN COMFORT SLIP XL Day/Night	I	1	18756INCCT0401JS
0910-A	ABSORIN COMFORT SLIP S Night/Heavy	I	1	18756INCCT0401JS
0920-A	ABSORIN COMFORT SLIP M Night/H	I	1	18756INCCT0401JS
0930-A	ABSORIN COMFORT SLIP L Night/H	I	1	18756INCCT0401JS
0940-A	ABSORIN COMFORT SLIP XL Night/H	I	1	18756INCCT0401JS
1022-A	ABSORIN COMFORT SLIP M Ultra	I	1	18756INCCT0401JS
1032-A	ABSORIN COMFORT SLIP L Ultra	I	1	18756INCCT0401JS
10511205	ABSORIN COMFORT PANTS PLUS XS	I	1	18756INCCT0401JS
10511275	ABSORIN COMFORT PANTS SUPER M	I	1	18756INCCT0401JS
10511285	ABSORIN COMFORT PANTS SUPER L	I	1	18756INCCT0401JS
10511295	ABSORIN COMFORT PANTS SUPER XL	I	1	18756INCCT0401JS
10511315	ABSORIN COMFORT PANTS FIT S	I	1	18756INCCT0401JS
10511325	ABSORIN COMFORT PANTS FIT M	I	1	18756INCCT0401JS
10511335	ABSORIN COMFORT PANTS FIT L	I	1	18756INCCT0401JS
10511345	ABSORIN COMFORT PANTS FIT XL	I	1	18756INCCT0401JS
10516200	ABSORIN COMFORT FINETTE ULTRA MINI	I	1	18756INCCT0401JS
10516206	ABSORIN COMFORT FINETTE MINI	I	1	18756INCCT0401JS
10516211	ABSORIN COMFORT FINETTE MINI PLUS	I	1	18756INCCT0401JS
10516215	ABSORIN COMFORT FINETTE NORMAL	I	1	18756INCCT0401JS

Product list related to DoC MD Class I – Absorbing Incontinence

Ref Nr	Article Description	Class	Rule	BASIC UDI-DI
10516225	ABSORIN COMFORT FINETTE EXTRA	I	1	18756INCCT0401JS
10516235	ABSORIN COMFORT FINETTE SUPER	I	1	18756INCCT0401JS
10516601	ABSORIN COMFORT LEVEL 2 MEN	I	1	18756INCCT0401JS
10519825	ABSORIN T-FIT DAY X-LARGE	I	1	18756INCCT0401JS
10519025	ABSORIN T-FIT DAY SMALL	I	1	18756INCCT0401JS
10519835	ABSORIN T-FIT NIGHT X-LARGE	I	1	18756INCCT0401JS
10519035	ABSORIN T-FIT NIGHT SMALL	I	1	18756INCCT0401JS
10519845	ABSORIN T-FIT HEAVY X-LARGE	I	1	18756INCCT0401JS
1225-A	ABSORIN COMFORT PANTS PLUS M	I	1	18756INCCT0401JS
1235-A	ABSORIN COMFORT PANTS PLUS L	I	1	18756INCCT0401JS
1245-A	ABSORIN COMFORT PANTS PLUS XL	I	1	18756INCCT0401JS
1580	ABSORIN WASHABLE UNDERPAD WITH TUCK-IN FLAPS 85X95CM	I	1	18756INCCT0401JS
4015	ABSORIN STRETCHSLIP EXTRA STRETCH S	I	1	18756INCCT0499L5
4020	ABSORIN STRETCHSLIP NORMAL STRETCH S	I	1	18756INCCT0499L5
4025	ABSORIN STRETCHSLIP EXTRA STRETCH M	I	1	18756INCCT0499L5
4030	ABSORIN STRETCHSLIP NORMAL STRETCH M	I	1	18756INCCT0499L5
4035	ABSORIN STRETCHSLIP EXTRA STRETCH L	I	1	18756INCCT0499L5
4040	ABSORIN STRETCHSLIP NORMALSTRETCH L	I	1	18756INCCT0499L5
4042	ABSORIN STRETCHSLIP NORMAL STRETCH XL.	I	1	18756INCCT0499L5
4045	ABSORIN STRETCHSLIP EXTRA STRETCH XL.	I	1	18756INCCT0499L5
4050	ABSORIN STRETCHSLIP NORMAL STRETCH XXL.	I	1	18756INCCT0499L5
4055	ABSORIN STRETCHSLIP EXTRA STRETCH XXL.	I	1	18756INCCT0499L5
4082	ABSORIN COMFORT STRETCHSLIP MICRO COMFORT S/M	I	1	18756INCCT0499L5
4084	ABSORIN COMFORT STRETCHSLIP MICRO COMFORT L/XL	I	1	18756INCCT0499L5
4136	ABSORIN TWINCO UNDERPAD DISPOSABLE WITH TUCK-IN FLAPS 180X80CM	I	1	18756INCCT0499L5
6400	ABSORIN MINCY LIGHT	I	1	18756INCCT0401JS
6500	ABSORIN MINCY NORMAL	I	1	18756INCCT0401JS
7045	ABSORIN CLASSIC INLAY MIDI	I	1	18756INCCT0401JS

Product list related to DoC MD Class I – Absorbing Incontinence

Ref Nr	Article Description	Class	Rule	BASIC UDI-DI
7050	ABSORIN CLASSIC INLAY MAXI	I	1	18756INCCT0401JS
10517308	ABSORIN COMFORT SANETTE DAY LIGHT	I	1	18756INCCT0401JS
10517310	ABSORIN COMFORT SANETTE DAY	I	1	18756INCCT0401JS
10517320	ABSORIN COMFORT SANETTE DAY EXTRA	I	1	18756INCCT0401JS
10517330	ABSORIN COMFORT SANETTE NIGHT	I	1	18756INCCT0401JS
10517340	ABSORIN COMFORT SANETTE NIGH HEAVY	I	1	18756INCCT0401JS
10517350	ABSORIN COMFORT SANETTE NIGHT ULTRA	I	1	18756INCCT0401JS
10516245	ABSORIN COMFORT FINETTE MAXI	I	1	18756INCCT0401JS
10516255	ABSORIN COMFORT FINETTE MAXI NIGHT	I	1	18756INCCT0401JS
10519125	ABSORIN T-FIT DAY MEDIUM	I	1	18756INCCT0401JS
10519325	ABSORIN T-FIT NIGHT MEDIUM	I	1	18756INCCT0401JS
10519725	ABSORIN T-FIT HEAVY MEDIUM	I	1	18756INCCT0401JS
10519135	ABSORIN T-FIT DAY LARGE	I	1	18756INCCT0401JS
10519335	ABSORIN T-FIT NIGHT LARGE	I	1	18756INCCT0401JS
10519735	ABSORIN T-FIT HEAVY LARGE	I	1	18756INCCT0401JS
10519925	ABSORIN T-FIT ULTRA MEDIUM	I	1	18756INCCT0401JS
10519935	ABSORIN T-FIT ULTRA LARGE	I	1	18756INCCT0401JS
10534060	ABSORIN COMFORT UNDERPAD NORMAL 40x60	I	1	18756INCCT0499L5
10534062	ABSORIN COMFORT UNDERPAD EXTRA 40x60	I	1	18756INCCT0499L5
10536060	ABSORIN COMFORT UNDERPAD NORMAL 60x60	I	1	18756INCCT0499L5
10536062	ABSORIN COMFORT UNDERPAD EXTRA 60x60	I	1	18756INCCT0499L5
10536090	ABSORIN COMFORT UNDERPAD NORMAL 60x90	I	1	18756INCCT0499L5
10536092	ABSORIN COMFORT UNDERPAD EXTRA 60x90	I	1	18756INCCT0499L5
10537308	ABSORIN COMFORT DAY LIGHT	I	1	18756INCCT0401JS
10537310	ABSORIN COMFORT DAY	I	1	18756INCCT0401JS
10537320	ABSORIN COMFORT DAY EXTRA	I	1	18756INCCT0401JS
10537330	ABSORIN COMFORT NIGHT	I	1	18756INCCT0401JS
10537340	ABSORIN COMFORT NIGHT HEAVY	I	1	18756INCCT0401JS

Product list related to DoC MD Class I – Absorbing Incontinence

Ref Nr	Article Description	Class	Rule	BASIC UDI-DI
10537350	ABSORIN COMFORT NIGHT ULTRA	I	1	18756INCCT0401JS
10511240	ABSORIN COMFORT PANTS SLIMFIT L	I	1	18756INCCT0401JS
10511230	ABSORIN COMFORT PANTS SLIMFIT M	I	1	18756INCCT0401JS
10511255	ABSORIN COMFORT PANTS PLUS XXL	I	1	18756INCCT0401JS
10511305	ABSORIN COMFORT PANTS SUPER XXL	I	1	18756INCCT0401JS
1042-A	ABSORIN COMFORT SLIP XL Ultra	I	1	18756INCCT0401JS
10531274	ABSORIN PANTS SUPER S	I	1	18756INCCT0401JS