

Manufacturer's EU Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Issuer's name : Medeco BV
Chamber of Commerce Registration # 23038479

Issuer's address : Alexander Flemingstraat 2
3261MA Oud Beijerland
The Netherlands

Object of the declaration : Woundcare and bandages

Single registration number : NL-MF-000001628

Classification : REGULATION (EU) 2017/745 Annex VIII, see attached Product list

Conformity assessment : REGULATION (EU) 2017/745 Annex II and Annex III

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.

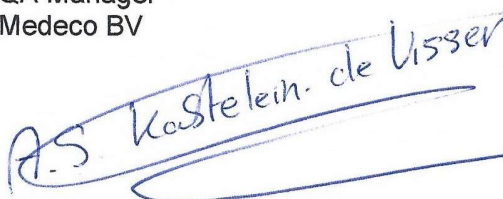
Hereby Medeco BV declares that the distributed products as specified in the annexed product list meet the provisions of the Council Regulation 2017/745 of 5 April 2017 on Medical Devices and comply to all harmonized standards which are applicable to the products, as published in the Official Journal of the European Union. Medeco BV further declares that it is exclusively responsible for this declaration of conformity.

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.

Oud Beijerland, 2 December 2021

Name : A.S. Kastelein – de Visser
Function : QA Manager
Medeco BV

Signature :



Product list related to DoC MD Class I – Woundcare and bandages

Ref Nr	Article Description	Class	Rule	BASIC UDI-DI
40512080	KLINIPRESS HG GAUZE COMPRESS 5X5CM 8L	I	4	18756KLHGM0201LL
40512081	KLINIPRESS HG GAUZE COMPRESS 7.5X7.5CM 8L	I	4	18756KLHGM0201LL
40512082	KLINIPRESS HG GAUZE COMPRESS 10X10CM 8L	I	4	18756KLHGM0201LL
40514870	KLINIDERM FILM ROLL 5cmx10m	I	4	18756KLFLM0401MV
40514871	KLINIDERM FILM ROLL 10cmx10m	I	4	18756KLFLM0401MV
40514872	KLINIDERM FILM ROLL 15cmx10m	I	4	18756KLFLM0401MV
40514873	KLINIDERM FILM 5x7.2cm 2 PCS	I	4	18756KLFLM0401MV
40514874	KLINIDERM FILM 5x7.2cm 12 PCS	I	4	18756KLFLM0401MV
40516002	KLINIDUR SHORT STRETCH 8CMx5M	I	1	18756KLFXM0304SS
40516003	KLINIDUR SHORT STRETCH 10CMx5M	I	1	18756KLFXM0304SS
40516004	KLINIDUR SHORT STRETCH 12CMx5M	I	1	18756KLFXM0304SS
111025	KLINIPRESS HG GAUZE COMPRESS 5X5CM 8L 100 PCS	I	4	18756KLHGM0201LL
111027	KLINIPRESS HG GAUZE COMPRESS 5X5CM 12L 50 PCS	I	4	18756KLHGM0201LL
111028	KLINIPRESS HG GAUZE COMPRESS 5X5CM 12L 100 PCS	I	4	18756KLHGM0201LL
111029	KLINIPRESS HG GAUZE COMPRESS 7.5X7.5CM, 12L	I	4	18756KLHGM0201LL
111030	KLINIPRESS HG GAUZE COMPRESS 7.5X7.5CM, 8L	I	4	18756KLHGM0201LL
111098	KLINIPRESS HG GAUZE COMPRESS 10X10CM 8L 100 PCS	I	4	18756KLHGM0201LL
111100	KLINIPRESS HG GAUZE COMPRESS 10X10CM 12L 50 PCS	I	4	18756KLHGM0201LL
111101	KLINIPRESS HG GAUZE COMPRESS 10X10CM 12L 100 PCS	I	4	18756KLHGM0201LL
111124	KLINIPRESS HG GAUZE COMPRESS 10X20CM 12L 50 PCS	I	4	18756KLHGM0201LL
111182	KLINIPRESS HG GAUZE COMPRESS 10X10CM 12L ANESTH	I	4	18756KLHGM0201LL
132101	KLINIGRIP TRICOT 20MX5CM	I	1	18756KLFXM0303SQ
132102	KLINIGRIP TRICOT 20MX7.5CM	I	1	18756KLFXM0303SQ
132103	KLINIGRIP TRICOT 20MX10CM	I	1	18756KLFXM0303SQ
132108	KLINIGRIP TRICOT 20MX30CM	I	1	18756KLFXM0303SQ
132215	KLINIGRIP TRICOT S 4MX10CM	I	1	18756KLFXM0303SQ
132216	KLINIGRIP TRICOT S 4MX12CM	I	1	18756KLFXM0303SQ
132217	KLINIGRIP TRICOT S 4MX15CM	I	1	18756KLFXM0303SQ

Product list related to DoC MD Class I – Woundcare and bandages

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132218	KLINIGRIP TRICOT S 4MX20CM	I	1	18756KLFXXM0303SQ
132330	KLINIFIX CREPE 4MX6CM	I	1	18756KLFXXM0303SQ
132331	KLINIFIX CREPE 4MX8CM	I	1	18756KLFXXM0303SQ
132332	KLINIFIX CREPE 4MX10CM	I	1	18756KLFXXM0303SQ
132334	KLINIFIX CREPE 4MX15CM	I	1	18756KLFXXM0303SQ
132378	KLINIFIX COHESIVE 4MX4CM	I	1	18756KLFXXM0304SS
132386	KLINIFIX COHESIVE 20MX6CM	I	1	18756KLFXXM0304SS
132387	KLINIFIX COHESIVE 20MX8CM	I	1	18756KLFXXM0304SS
132388	KLINIFIX COHESIVE 20MX10CM	I	1	18756KLFXXM0304SS
132377	KLINIFIX COHESIVE 4MX2.5CM	I	1	18756KLFXXM0304SS
132440	KLINIGRIP IDEAL 5MX4CM	I	1	18756KLFXXM0303SQ
132441	KLINIGRIP IDEAL 5MX6CM	I	1	18756KLFXXM0303SQ
132442	KLINIGRIP IDEAL 5MX 8CM	I	1	18756KLFXXM0303SQ
132443	KLINIGRIP IDEAL 5MX10CM	I	1	18756KLFXXM0303SQ
132444	KLINIGRIP IDEAL 5MX12CM	I	1	18756KLFXXM0303SQ
132581	KLINIGRIP LA SUPPORT ADJUSTABLE S	I	1	18756KLFXXM0303SQ
132582	KLINIGRIP LA SUPPORT ADJUSTABLE M	I	1	18756KLFXXM0303SQ
132583	KLINIGRIP LA SUPPORT ADJUSTABLE L	I	1	18756KLFXXM0303SQ
132584	KLINIGRIP LA SUPPORT ADJUSTABLE XL	I	1	18756KLFXXM0303SQ
132590	KLINIGRIP ARM SLING FOAM 5.5CMX12M	I	1	18756KLBDM0301GC
132591	KLINIGRIP ARM SLING FOAM 5.5CMX1.9M	I	1	18756KLBDM0301GC
170067	KLINIPRESS EXSUPAD 20X30CM	I	4	18756KLADM040204SY
170069	KLINIPRESS EXSUPAD 20X40CM	I	4	18756KLADM040204SY
170070	KLINIPRESS EXSUPAD 10X20CM 25ST	I	4	18756KLADM040204SY
170072	KLINIPRESS EXSUPAD 10X20CM 50ST	I	4	18756KLADM040204SY
170073	KLINIPRESS EXSUPAD 20X20CM	I	4	18756KLADM040204SY
170075	KLINIPRESS EXSUPAD 9X12CM	I	4	18756KLADM040204SY
175004	KLINIPRESS NW COMPRESS 5X5CM 4L 100 PCS	I	4	18756KLNNWM0202WC

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175024	KLINIPRESS NW COMPRESS 7,5X7,5CM 4L 100 PCS	I	4	18756KLNWWM0202WC
175034	KLINIPRESS NW COMPRESS 10X10CM 4L 100 PCS	I	4	18756KLNWWM0202WC
175035	KLINIPRESS NW COMPRESS 10X10CM 4L 50ST PCS	I	4	18756KLNWWM0202WC
175043	KLINIPRESS NW COMPRESS 10X20CM 4L 100 PCS	I	4	18756KLNWWM0202WC
175104	KLINIPRESS NW COMPRESS 5X5CM 8L XTR 100 PCS	I	4	18756KLNWWM0202WC
175134	KLINIPRESS NW COMPRESS 10X10CM 8L XTR 100 PCS	I	4	18756KLNWWM0202WC
176000	KLINIPRESS ABSORBENT DRESSING PULP CORE 10x10 100ST	I	4	18756KLADM040204SY
176001	KLINIPRESS ABSORBENT DRESSING PULP CORE 10x20 25ST	I	4	18756KLADM040204SY
176002	KLINIPRESS ABSORBENT DRESSING PULP CORE 20x20 20ST	I	4	18756KLADM040204SY
294152	KLINIPLAST NW DISP 9,1MX2,50CM	I	1	18756KLTPM0502X6
294155	KLINIPLAST NW 9,1MX1,25CM	I	1	18756KLTPM0502X6
294156	KLINIPLAST NW 9,1MX2,50CM	I	1	18756KLTPM0502X6
294160	KLINIPLAST TEXTILE 5MX1,25CM	I	1	18756KLTPM0502X6
294161	KLINIPLAST TEXTILE 5MX2,50CM	I	1	18756KLTPM0502X6
294166	KLINIPLAST TEXTILE 9,1MX2,50CM	I	1	18756KLTPM0502X6
294167	KLINIPLAST TEXTILE 9,1MX5CM	I	1	18756KLTPM0502X6
294175	KLINIPLAST NW 5MX1,25CM M RING	I	1	18756KLTPM0502X6
294176	KLINIPLAST NW 5MX2,50CM M RING	I	1	18756KLTPM0502X6
294179	KLINIPLAST NW 5MX5CM M RING	I	1	18756KLTPM0502X6
294180	KLINIPLAST SILK 5MX1,25	I	1	18756KLTPM0502X6
294181	KLINIPLAST SILK 5MX2,50	I	1	18756KLTPM0502X6
294186	KLINIPLAST SILK 9,1MX2,50CM	I	1	18756KLTPM0502X6
294190	KLINIPLAST TRANSPAR 5MX1,25CM	I	1	18756KLTPM0502X6
294191	KLINIPLAST TRANSPAR 5MX2,50CM	I	1	18756KLTPM0502X6
294340	KLINIPLAST FIXATION PLASTER 10MX 5CM	I	1	18756KLTPM0502X6
294342	KLINIPLAST FIXATION PLASTER 10MX10CM	I	1	18756KLTPM0502X6
294344	KLINIPLAST FIXATION PLASTER 10MX15CM	I	1	18756KLTPM0502X6

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294346	KLINIPLAST FIXATION PLASTER 10MX20CM	I	1	18756KLTPM0502X6
102026	KLINIGRIP ARM SLING NW	I	1	18756KLBDM0301GC
102027	KLINIGRIP ARM SLING TEXTILE	I	1	18756KLBDM0301GC
40571410	KLINIFIX ECO-CREPE BANDAGE 4MX5CM	I	1	18756KLBDM0301GC
40571420	KLINIFIX ECO-CREPE BANDAGE 4MX7CM	I	1	18756KLBDM0301GC
40571430	KLINIFIX ECO-CREPE BANDAGE 4MX10CM	I	1	18756KLBDM0301GC
40571440	KLINIFIX ECO-CREPE BANDAGE 4MX15CM	I	1	18756KLBDM0301GC
132401	KLINIGRIP COHESIVE 4,5MX 6CM	I	1	18756KLFXM0303SQ
132402	KLINIGRIP COHESIVE 4,5MX 8CM	I	1	18756KLFXM0303SQ
132403	KLINIGRIP COHESIVE 4,5MX10CM	I	1	18756KLFXM0303SQ
132379	KLINIFIX COHESIVE 4MX6CM	I	1	18756KLBDM0301GC
132380	KLINIFIX COHESIVE 4MX8CM	I	1	18756KLBDM0301GC
132381	KLINIFIX COHESIVE 4MX10CM	I	1	18756KLBDM0301GC
132382	KLINIFIX COHESIVE 4MX12CM	I	1	18756KLBDM0301GC
132445	KLINIGRIP IDEAL 5MX15CM	I	1	18756KLFXM0303SQ
294157	KLINIPLAST NW TAPE 9,1X5CM	I	1	18756KLTPM0502X6
294185	KLINIPLAST SILK TAPE 9,1X1,25CM	I	1	18756KLTPM0502X6
294165	KLINIPLAST TEXTILE 9,1X1,25CM	I	1	18756KLTPM0502X6
294154	KLINIPLAST NW DISP LUXE 5MX2,50CM	I	1	18756KLTPM0502X6
40294375	KLINIPLAST Injection Plaster 20x60mm	I	4	18756KLTPM0502X6
40132283	KLINIFIX NON-ELASTIC BANDAGE 4MX8CM	I	1	18756KLBDM0301GC
40132230	KLINIFIX ELASTIC BANDAGE 4MX10CM	I	1	18756KLFXM0303SQ
40132229	KLINIFIX ELASTIC BANDAGE 4MX8CM	I	1	18756KLFXM0303SQ
40132228	KLINIFIX ELASTIC BANDAGE 4MX6CM	I	1	18756KLFXM0303SQ
40132281	KLINIFIX NON-ELASTIC BANDAGE 4MX4CM	I	1	18756KLBDM0301GC
40132231	KLINIFIX ELASTIC BANDAGE 4MX12CM	I	1	18756KLFXM0303SQ
40132284	KLINIFIX NON-ELASTIC BANDAGE 4MX10CM	I	1	18756KLBDM0301GC
40132282	KLINIFIX NON-ELASTIC BANDAGE 4MX6CM	I	1	18756KLBDM0301GC

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40132227	KLINIFIX ELASTIC BANDAGE 4MX4CM	I	1	18756KLFXXM0303SQ
40170094	KLINION CELLULOSE SWABS 4X5CM	I	1	18756KLADM040204SY
40170060	KLINION COTTON SHEET FOR OINTMENT APPLICATION (ENGELS PLUKSEL) 10CMX5M	I	1	18756KLBDM0301GC
40170058	KLINION COTTON SHEET FOR OINTMENT APPLICATION (ENGELS PLUKSEL) 45CMX5M	I	1	18756KLBDM0301GC
40141091	KLINISOFT SYNTHETIC PADDING 10CMX3M	I	1	18756KLSOM0102VL
40141090	KLINISOFT SYNTHETIC PADDING 6CMX3M	I	1	18756KLSOM0102VL
40141092	KLINISOFT SYNTHETIC PADDING 15CMX3M	I	1	18756KLSOM0102VL
132363	KLINIDUR FORTE LONG STRETCH 7MX12CM	I	1	18756KLFXXM0304SS
132346	KLINIDUR STANDARD LONG STRETCH 7MX8CM	I	1	18756KLFXXM0304SS
132347	KLINIDUR STANDARD LONG STRETCH 7MX10CM	I	1	18756KLFXXM0304SS
132361	KLINIDUR FORTE LONG STRETCH 7MX8CM	I	1	18756KLFXXM0304SS
132362	KLINIDUR FORTE LONG STRETCH 7MX10CM	I	1	18756KLFXXM0304SS
132628	KLINIDUR TEXTELAST SHORT STRETCH 5MX8CM	I	1	18756KLFXXM0304SS
132630	KLINIDUR TEXTELAST SHORT STRETCH 5MX10CM	I	1	18756KLFXXM0304SS