

Manufacturer's 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

Classification : According to MDD Annex IX, Class I

Conformity assessment : MDD Annex V/VII

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 MDD 93/42/EEC Medical Device Directive: Council Directive 93/42/EEC concerning medical devices June 14th, 1993 as amended by directive 2007/47/EC 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 UK. The applied standards for this family of products is maintained in the Technical Dossier.

Oud Beijerland, 9 July 2019

Name : F.H.M. Dekker
Function : Regulatory Affairs Manager
Medeco BV

Signature :



Product list related to DoC MD Class I - Woundcare and Bandages

REF nr	Article nr	Description	Class	Rule
40514870	3016568	KLINIDERM FILM ROLL 5cmx10m		4
40514871	3016569	KLINIDERM FILM ROLL 10cmx10m		4
40514872	3016570	KLINIDERM FILM ROLL 15cmx10m		4
40516000	3016594	KLINIDUR SHORT STRETCH 4CMx5M		1
40516001	3016595	KLINIDUR SHORT STRETCH 6CMx5M		1
40516002	3016596	KLINIDUR SHORT STRETCH 8CMx5M		1
40516003	3016597	KLINIDUR SHORT STRETCH 10CMx5M		1
40516004	3016598	KLINIDUR SHORT STRETCH 12CMx5M		1
132346	3016825	KLINIDUR STANDARD 7MX8CM		1
132347	3016826	KLINIDUR STANDARD 7MX10CM		1
132361	3016827	KLINIDUR FORTE 7MX8CM		1
132362	3016828	KLINIDUR FORTE 7MX10CM		1
132363	3016829	KLINIDUR FORTE 7MX12CM		1
132628	3016876	KLINIDUR TEXTELAST 5MX 8CM		1
132630	3016877	KLINIDUR TEXTELAST 5MX10CM		1
40571410	3038412	KLINIFIX ECO-CREPE BANDAGE 4MX5CM		1
40571420	3038413	KLINIFIX ECO-CREPE BANDAGE 4MX7CM		1
40571430	3038415	KLINIFIX ECO-CREPE BANDAGE 4MX10CM		1
40571440	3038417	KLINIFIX ECO-CREPE BANDAGE 4MX15CM		1
40132281	3052460	KLINIFIX NON-ELASTIC BANDAGE 4MX4CM		4
40132282	3052464	KLINIFIX NON-ELASTIC BANDAGE 4MX6CM		4
40132283	3052456	KLINIFIX NON-ELASTIC BANDAGE 4MX8CM		4
40132284	3052463	KLINIFIX NON-ELASTIC BANDAGE 4MX10CM		4
40132227	3052465	KLINIFIX ELASTIC BANDAGE 4MX4CM		4
40132228	3052459	KLINIFIX ELASTIC BANDAGE 4MX6CM		4
40132229	3052458	KLINIFIX ELASTIC BANDAGE 4MX8CM		4
40132230	3052457	KLINIFIX ELASTIC BANDAGE 4MX10CM		4
40132231	3052461	KLINIFIX ELASTIC BANDAGE 4MX12CM		4
132227	3016803	KLINIFIX HYDROLAST 4MX 4CM		1
132228	3016804	KLINIFIX HYDROLAST 4MX 6CM		1
132229	3016805	KLINIFIX HYDROLAST 4MX 8CM		1
132230	3016806	KLINIFIX HYDROLAST 4MX10CM		1
132231	3016807	KLINIFIX HYDROLAST 4MX12CM		1
132377	3016838	KLINIFIX COHESIVE 4MX2.5CM		1
132378	3016830	KLINIFIX COHESIVE 4MX4CM		1
132379	3038996	KLINIFIX COHESIVE 4MX6CM		1
132380	3038997	KLINIFIX COHESIVE 4MX8CM		1
132381	3039000	KLINIFIX COHESIVE 4MX10CM		1
132382	3039001	KLINIFIX COHESIVE 4MX12CM		1
132386	3016835	KLINIFIX COHESIVE 20MX6CM		1
132387	3016836	KLINIFIX COHESIVE 20MX8CM		1
132388	3016837	KLINIFIX COHESIVE 20MX10CM		1
132330	3016820	KLINIFIX CREPE 4MX6CM		1
132331	3016821	KLINIFIX CREPE 4MX8CM		1
132332	3016822	KLINIFIX CREPE 4MX10CM		1
132334	3016824	KLINIFIX CREPE 4MX15CM		1
132401	3038970	KLINIGRIP COHESIVE 4,5MX 6CM		1
132401	3016839	KLINIGRIP COHESIVE 4,5MX 6CM		1
132402	3038994	KLINIGRIP COHESIVE 4,5MX 8CM		1
132403	3038995	KLINIGRIP COHESIVE 4,5MX10CM		1
132440	3016843	KLINIGRIP IDEAL 5MX4CM		1
132441	3016844	KLINIGRIP IDEAL 5MX6CM		1
132442	3016845	KLINIGRIP IDEAL 5MX 8CM		1
132443	3016847	KLINIGRIP IDEAL 5MX10CM		1
132444	3016849	KLINIGRIP IDEAL 5MX12CM		1
132445	3046591	KLINIGRIP IDEAL 5MX15CM		1
132101	3016787	KLINIGRIP TRICOT 20MX5CM		1
132102	3016788	KLINIGRIP TRICOT 20MX7.5CM		1
132103	3016789	KLINIGRIP TRICOT 20MX10CM		1
132108	3016792	KLINIGRIP TRICOT 20MX30CM		1
132215	3016796	KLINIGRIP TRICOT S 4MX10CM		1
132216	3016798	KLINIGRIP TRICOT S 4MX12CM		1
132217	3016800	KLINIGRIP TRICOT S 4MX15CM		1
132218	3016802	KLINIGRIP TRICOT S 4MX20CM		1
132581	3016857	KLINIGRIP LA SUPPORT ADJUSTABLE S		1
132582	3016858	KLINIGRIP LA SUPPORT ADJUSTABLE M		1
132583	3016859	KLINIGRIP LA SUPPORT ADJUSTABLE L		1
132584	3016860	KLINIGRIP LA SUPPORT ADJUSTABLE XL		1
102026	3038155	KLINIGRIP ARM SLING NW		1
102027	3038156	KLINIGRIP ARM SLING TEXTILE		1
132590	3016862	KLINIGRIP ARM SLING FOAM 5.5CMX12M		1
132591	3016863	KLINIGRIP ARM SLING FOAM 5.5CMX1.9M		1
111025	3016692	KLINIPRESS HG GAUZE COMPRESS 5X5CM 8L 100 PCS		4
111027	3016694	KLINIPRESS HG GAUZE COMPRESS 5X5CM 12L 50 PCS		4
111028	3016695	KLINIPRESS HG GAUZE COMPRESS 5X5CM 12L 100 PCS		4

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REF nr	Article nr	Description	Class	Rule
111098	3016712	KLINIPRESS HG GAUZE COMPRESS 10X10CM 8L 100 PCS		4
111100	3016713	KLINIPRESS HG GAUZE COMPRESS 10X10CM 12L 50 PCS		4
111101	3016714	KLINIPRESS HG GAUZE COMPRESS 10X10CM 12L 100 PCS		4
111124	3016718	KLINIPRESS HG GAUZE COMPRESS 10X20CM 12L 50 PCS		4
111029	3016696	KLINIPRESS HG GAUZE COMPRESS 7.5X7.5CM, 12L		4
111030	3016697	KLINIPRESS HG GAUZE COMPRESS 7.5X7.5CM, 8L		4
111182	3016721	KLINIPRESS HG GAUZE COMPRESS 10X10CM 12L ANESTH		4
40512080	3016483	KLINIPRESS HG GAUZE COMPRESS 5X5CM 8L		4
40512081	3016484	KLINIPRESS HG GAUZE COMPRESS 7.5X7.5CM 8L		4
40512082	3016485	KLINIPRESS HG GAUZE COMPRESS 10X10CM 8L		4
40512050	3016471	KLINIPRESS NW COMPRESS 5X5CM 4L		4
40512051	3016472	KLINIPRESS NW COMPRESS 7.5X7.5CM 4L		4
40512052	3016473	KLINIPRESS NW COMPRESS 10X10CM 4L		4
175004	3017047	KLINIPRESS NW COMPRESS 5X5CM 4L 100 PCS		4
175024	3017051	KLINIPRESS NW COMPRESS 7,5X7,5CM 4L 100 PCS		4
175034	3017056	KLINIPRESS NW COMPRESS 10X10CM 4L 100 PCS		4
175035	3017057	KLINIPRESS NW COMPRESS 10X10CM 4L 50ST PCS		4
175043	3017061	KLINIPRESS NW COMPRESS 10X20CM 4L 100 PCS		4
175104	3017072	KLINIPRESS NW COMPRESS 5X5CM 8L XTR 100 PCS		4
175134	3017078	KLINIPRESS NW COMPRESS 10X10CM 8L XTR 100 PCS		4
170067	3016974	KLINIPRESS EXSUPAD 20X30CM		4
170069	3016975	KLINIPRESS EXSUPAD 20X40CM		4
170070	3016976	KLINIPRESS EXSUPAD 10X20CM 25ST		4
170072	3016977	KLINIPRESS EXSUPAD 10X20CM 50ST		4
170073	3016978	KLINIPRESS EXSUPAD 20X20CM		4
170075	3016979	KLINIPRESS EXSUPAD 9X12CM		4
4176000	3017081	KLINIPRESS ABSORBENT DRESSING PULP CORE 10x10 100ST		4
4176001	3017082	KLINIPRESS ABSORBENT DRESSING PULP CORE 10x20 25ST		4
4176002	3017083	KLINIPRESS ABSORBENT DRESSING PULP CORE 20x20 20ST		4
294119	3017098	KLINIPLAST KIDS GARF 20 STRIP		4
294120	3017099	KLINIPLAST KIDS GARF 100 STRIP		4
294121	3017100	KLINIPLAST DETECTABLE BLUE		4
294152	3017105	KLINIPLAST NW DISP 9,1MX2,50CM		4
294153	3046844	KLINIPLAST NW DISP LUXE 5MX2,50CM		4
294155	3017106	KLINIPLAST NW 9,1MX1,25CM		4
294156	3017107	KLINIPLAST NW 9,1MX2,50CM		4
294157	3046594	KLINIPLAST NW TAPE 9,1X5CM		4
294160	3017108	KLINIPLAST TEXTILE 5MX1,25CM		4
294161	3017109	KLINIPLAST TEXTILE 5MX2,50CM		4
294165	3046597	KLINIPLAST TEXTILE 9,1X1,25CM		4
294166	3017110	KLINIPLAST TEXTILE 9,1MX2,50CM		4
294167	3017111	KLINIPLAST TEXTILE 9,1MX5CM		4
294175	3017112	KLINIPLAST NW 5MX1,25CM M RING		4
294176	3017113	KLINIPLAST NW 5MX2,50CM M RING		4
294179	3017114	KLINIPLAST NW 5MX5CM M RING		4
294180	3017115	KLINIPLAST SILK 5MX1,25		4
294181	3017116	KLINIPLAST SILK 5MX2,50		4
294185	3046596	KLINIPLAST SILK TAPE 9,1X1,25CM		4
294186	3017117	KLINIPLAST SILK 9,1MX2,50CM		4
294190	3017118	KLINIPLAST TRANSPAR 5MX1,25CM		4
294191	3017119	KLINIPLAST TRANSPAR 5MX2,50CM		4
40294375	3052162	KLINIPLAST Injection Plaster 20x60mm		4
294340	3017126	KLINIPLAST FIXATION PLASTER 10MX 5CM		4
294342	3017127	KLINIPLAST FIXATION PLASTER 10MX10CM		4
294344	3017128	KLINIPLAST FIXATION PLASTER 10MX15CM		4
294346	3017129	KLINIPLAST FIXATION PLASTER 10MX20CM		4
40141091	3052513	KLINISOFT SYNTHETIC PADDING 10CMX3M		1
40141090	3052514	KLINISOFT SYNTHETIC PADDING 6CMX3M		1
40141092	3052515	KLINISOFT SYNTHETIC PADDING 15CMX3M		1
40170094	3052494	KLINION CELLULOSE SWABS 4X5CM		1
4165002	3016923	KLINIFIX ELASTIC FIXATION BANDAGE 4MX4CM		4
4165003	3016924	KLINIFIX ELASTIC FIXATION BANDAGE 4MX6CM		4
4165004	3016925	KLINIFIX ELASTIC FIXATION BANDAGE 4MX8CM		4
4165005	3016926	KLINIFIX ELASTIC FIXATION BANDAGE 4MX10CM		4
4165006	3016927	KLINIFIX ELASTIC FIXATION BANDAGE 4MX12CM		4
40515002	3016578	KLINIFIX ELASTIC FIXATION BANDAGE Bulk 4Mx4CM		4
40515003	3016579	KLINIFIX ELASTIC FIXATION BANDAGE Bulk 4Mx6CM		4
40515004	3016580	KLINIFIX ELASTIC FIXATION BANDAGE Bulk 4Mx8CM		4
40515005	3016581	KLINIFIX ELASTIC FIXATION BANDAGE Bulk 4MX10CM		4
40515006	3016582	KLINIFIX ELASTIC FIXATION BANDAGE Bulk 4MX12CM		4
132290	3016818	KLINIFIX HEAD READY-TO-USE ELASTIC DRESSING S		4
132291	3016819	KLINIFIX HEAD READY-TO-USE ELASTIC HEAD DRESSING L		4
132281	3016814	KLINIFIX HYDROPHILE 4MX 4CM		4
132282	3016815	KLINIFIX HYDROPHILE 4MX 6CM		4
132283	3016816	KLINIFIX HYDROPHILE 4MX 8CM		4

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REF nr	Article nr	Description	Class	Rule
132284	3016817	KLINIFIX HYDROPHILE 4MX10CM		4
132257	3016811	KLINIFIX CAMBRIC 4MX6CM		1
132258	3016812	KLINIFIX CAMBRIC 4MX8CM		1
132259	3016813	KLINIFIX CAMBRIC 4MX10CM		1
170057	3016971	KLINION COTTON SHEET FOR OINTMENT APPLICATION (ENGELS PLUKSEL		4
170058	3016972	KLINION COTTON SHEET FOR OINTMENT APPLICATION (ENGELS PLUKSEL		4
170060	3016973	KLINION COTTON SHEET FOR OINTMENT APPLICATION (ENGELS PLUKSEL		4
170941	3016991	KLINION CELLULOSE SWAB 4X5CM ROLL 500 PCS		1
294375	3017133	KLINIPLAST INJECTION ROLL 20X40MM		4
294380	3017134	KLINIPLAST SENSITIVE SOFT NW WOUND PLASTER STRIPS ROLL20X60MM		4
141090	3050294	KLINISOFT SY 3MX 6CM		1
141091	3016911	KLINISOFT SY 3MX10CM		1
141092	3016912	KLINISOFT SY 3MX15CM		1
124121	3016771	KLINISOFT STANDARD 10G IN ZAK		4
124124	3016774	KLINISOFT STANDARD 100G IN ZAK		4
124125	3016775	KLINISOFT STANDARD 250G IN ZAK		4
124126	3016776	KLINISOFT STANDARD 500G IN ZAK		4
141016	3016902	KLINISOFT STANDARD 1KG ROLL		4
141030	3016903	KLINISOFT STANDARD 2MX6CM ROLL		4
141032	3016904	KLINISOFT STANDARD 2MX10CM ROLL		4
141051	3016905	KLINISOFT NATURAL 50GR		4
141052	3016906	KLINISOFT NATURAL 100GR		4
141068	3016909	KLINISOFT NATURAL 2MX10 OP ROL		4
145001	3016916	KLINISOFT BALLS 3 BAG 500G		4
145002	3016917	KLINISOFT BALLS 6 BAG 500G		4
145004	3016918	KLINISOFT BALLS 15 BAG 500G		4
145008	3016920	KLINISOFT BALLS 50 BAG 500G		4
103000	3016674	KLINITAPE 2.50CMX10M		1
103001	3016675	KLINITAPE 3.75CMX10M		1
132650	3016881	KLINIDUR ADHES ACRYL 4.5MX 6CM		1
132651	3016882	KLINIDUR ADHES ACRYL 4.5MX 8CM		1
132652	3016883	KLINIDUR ADHES ACRYL 4.5MX10CM		1
165017	3016938	KLINIDUR LONG STRETCH 7MX 8CM		1
165018	3016939	KLINIDUR LONG STRETCH 7MX 8CM		1
165019	3016940	KLINIDUR LONG STRETCH 7MX 8CM		1
132469	3016853	KLINIGRIP ECO-IDEAL 5MX 6CM		1
132470	3016854	KLINIGRIP ECO-IDEAL 5MX 8CM		1
132471	3016855	KLINIGRIP ECO-IDEAL 5MX10CM		1
132472	3016856	KLINIGRIP ECO-IDEAL 5MX12CM		1
294100	3017088	KLINIPLAST READY 1MX6CM		4
294101	3017089	KLINIPLAST READY ASSORTI		4
294103	3017090	KLINIPLAST EASY STRIP IN DISP		4
294105	3017092	KLINIPLAST READY 1MX6CM		4
294115	3017095	KLINIPLAST STAND SOFT 1MX6CM		4
294116	3017096	KLINIPLAST WATERPROOF PLASTER		4
294117	3017097	KLINIPLAST READY SOFT		4
294350	3017130	KLINIPLAST READY 5MX6CM		4
294351	3017131	KLINIPLAST READY 5MX6CM		4
294353	3017132	KLINIPLAST STAND SOFT 5MX6CM		4

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