

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 : Medical Devices for wound care and intraoperative use

UMDNS Code : See attached Product list

Classification : According to MDD Annex IX, see attached Product list

Conformity assessment : MDD Annex II

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.

Additional information

Notified Body : BSI, Notified Body Number 2797
Say Building, John M. Keynesplein 9,
1066 EP Amsterdam, The Netherlands

CE certificate : CE 607662

First Issue Date certificate : 24 June 2016

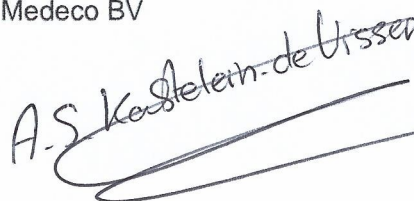
Validity : 26 May 2024

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 are maintained in the Technical Dossier.

Oud Beijerland, 14 April 2021

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

Signature :



UMDNS	REF nr	Article nr	Product Name	Class	Rule
11-326	174501	3049841	KLINIDERM ALGINATE 5X 5CM *S*	IIb	4
11-326	174502	3049842	KLINIDERM ALGINATE 10X10CM *S*	IIb	4
11-326	174503	3049843	KLINIDERM ALGINATE 10X20CM *S*	IIb	4
11-326	174515	3049844	KLINIDERM ALGIN CAVIT 30CM *S*	IIb	4
11-323	40514823	3016530	Kliniderm Foam 5 x 5 cm silicon	IIb	4
11-323	40514824	3016531	Kliniderm Foam 10 x 10 cm silicon	IIb	4
11-323	40514825	3016532	Kliniderm Foam 15 x 15 cm silicon	IIb	4
11-323	40514826	3016533	Kliniderm Foam 10 x 20 cm silicon	IIb	4
11-323	40514827	3016534	Kliniderm Foam 20 x 20 cm silicon	IIb	4
11-323	40514828	3016535	Kliniderm Foam 7.5 x 7.5 cm silicon border	IIb	4
11-323	40514829	3016536	Kliniderm Foam 10 x 10 cm silicon border	IIb	4
11-323	40514830	3016537	Kliniderm Foam 12.5 x 12.5 cm silicon border	IIb	4
11-323	40514831	3016538	Kliniderm Foam 15 x 15 cm silicon border	IIb	4
11-323	40514832	3016539	Kliniderm Foam 10 x 20 cm silicon border	IIb	4
11-323	40514833	3016540	Kliniderm Foam 10 x 30 cm silicon border	IIb	4
11-323	40514834	3016541	Kliniderm Foam 15 x 20 cm silicon border	IIb	4
11-323	40514810	3016521	Kliniderm Foam Lite silicone 6x8,5	IIb	4
11-323	40514811	3016522	Kliniderm Foam Lite silicone 10x10	IIb	4
11-323	40514812	3016523	Kliniderm Foam Lite silicone 15x15	IIb	4
11-323	40514813	3016524	Kliniderm Foam Lite silicone 20x50	IIb	4
11-323	40514814	3016525	Kliniderm Foam Lite silicone border 4x5	IIb	4
11-323	40514815	3016526	Kliniderm Foam Lite silicone border 5x12,5	IIb	4
11-323	40514816	3016527	Kliniderm Foam Lite silicone border 7.5x7.5	IIb	4
11-323	40514817	3016528	Kliniderm Foam Lite silicone border 10x10	IIb	4
11-323	40514818	3016529	Kliniderm Foam Lite silicone border 15x15	IIb	4
11-323	40514835	3016542	Kliniderm Foam silicone heel 10x17,5cm	IIb	4
11-323	40514836	3037336	Kliniderm Foam silicone heel border 20x20,8 cm	IIb	4
11-323	40514837	3016544	Kliniderm Foam silicone sacrum border 22.5x22.5cm	IIb	4
11-323	40514838	3016545	Kliniderm Foam silicone sacrum border 18x18cm	IIb	4
11-323	40514839	3016546	Kliniderm Foam silicone sacrum border 15x15cm	IIb	4
24-847	174101	3036414	KLINIDERM HYD THIN 7,5X7,5 *S*	IIb	4
24-847	174102	3036357	KLINIDERM HYDRO THIN 10X10 *S*	IIb	4
24-847	174103	3036358	KLINIDERM HYDRO THIN 15X15 *S*	IIb	4
24-847	174104	3036359	KLINIDERM HYDRO THIN 20X20 *S*	IIb	4
24-847	174201	3036391	KLINIDERM HYDRO BORD 7X 7 *S*	IIb	4
24-847	174202	3036394	KLINIDERM HYDRO BORD 10X10 *S*	IIb	4
24-847	174203	3036396	KLINIDERM HYDRO BORD 14X14 *S*	IIb	4
24-847	174204	3036398	KLINIDERM HY BORD S 15X18 *S*	IIb	4
24-847	174302	3036409	KLINIDERM HYDRO STAN 10X10 *S*	IIb	4
24-847	174303	3036410	KLINIDERM HYDRO STAN 15X15 *S*	IIb	4
24-847	174304	3036412	KLINIDERM HYDRO STAN 20X20 *S*	IIb	4
24-853	40514880	3016573	Kliniderm Silicone wound contact layer 5x7,5cm sterile	IIb	4
24-853	40514881	3016574	Kliniderm Silicone wound contact layer 7,5x10cm sterile	IIb	4
24-853	40514882	3016575	Kliniderm Silicone wound contact layer 10x18cm sterile	IIb	4
24-853	40514883	3016576	Kliniderm Silicone wound contact layer 20x30cm sterile	IIb	4
24-853	40514884	3016577	Kliniderm Silicone wound contact layer 17x25cm sterile	IIb	4
11-326	40511700	3016447	Klinion Kliniderm Superabsorbent dressing 7,5 x 7,5 cm sterile	IIb	4
11-326	40511701	3016448	Klinion Kliniderm Superabsorbent dressing 10 x 10 cm sterile	IIb	4
11-326	40511702	3016449	Klinion Kliniderm Superabsorbent dressing 10 x 20 cm sterile	IIb	4
11-326	40511703	3016450	Klinion Kliniderm Superabsorbent dressing 20 x 20 cm sterile	IIb	4
11-326	40511704	3016451	Klinion Kliniderm Superabsorbent dressing 20 x 30 cm sterile	IIb	4
11-326	40511710	3016456	Klinion Kliniderm Superabsorbent dressing 10 x 10 cm non ste	IIb	4
11-326	40511711	3016457	Klinion Kliniderm Superabsorbent dressing 10 x 20 cm non ste	IIb	4
11-326	40511712	3016458	Klinion Kliniderm Superabsorbent dressing 20 x 20 cm non ste	IIb	4
11-326	40511706	3016452	Klinion Kliniderm Superabsorbent dressing 10x10cm Sterile	IIb	4
11-326	40511707	3016453	Klinion Kliniderm Superabsorbent dressing 10x15cm Sterile	IIb	4
11-326	40511708	3016454	Klinion Kliniderm Superabsorbent dressing 15x20cm Sterile	IIb	4
11-326	40511705	3038381	Klinion Kliniderm Superabsorbent dressing 20x40cm Sterile	IIb	4
11-326	40511713	3051260	Klinion Kliniderm Superabsorbent dressing 10 x 20 cm sterile	IIb	4
11-323	40174810	3051275	Klinion Kliniderm Foam 5x5 cm	IIb	4
11-323	40174811	3051276	Klinion Kliniderm Foam 10x10 cm	IIb	4
11-323	40174812	3051278	Klinion Kliniderm Foam 15x15 cm	IIb	4
11-323	40174813	3051277	Klinion Kliniderm Foam 10x18 cm	IIb	4

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11-323	40174814	3051294	Klinion Kliniderm Foam 20x20 cm	IIb	4
11-323	40174815	3051279	Klinion Kliniderm Foam Border 7.5x7.5 cm	IIb	4
11-323	40174816	3051290	Klinion Kliniderm Foam Border 10x10 cm	IIb	4
11-323	40174819	3051291	Klinion Kliniderm Foam Border 12.5x12.5 cm	IIb	4
11-323	40174817	3051292	Klinion Kliniderm Foam Border 15x15 cm	IIb	4
11-323	40174820	3051293	Klinion Kliniderm Foam Heel	IIb	4
24-817	170097	3038895	Klinitulle ointment compress 5x5 cm sterile	IIa	4
24-817	170098	3035382	Klinitulle ointment compress 10x10 cm sterile	IIa	4
24-817	170099	3016980	Klinitulle ointment compress 10x30 cm sterile	IIa	4
13-705	111180	3016720	GAASK 10X10 12L X-RAY 50	IIa	7
13-705	111209	3016722	GAASK 10X20 12L X-RAY 50	IIa	7
13-705	111322	3016731	BUIKGAAS 45X70CM 4L X-RAY	IIa	7
13-705	115001	3016736	GAASK 5X 5 12L XRAY *S* PIP10	IIa	7
13-705	115005	3016737	GAASK 10X10 12L XRAY *S* PIP5	IIa	7
13-705	115007	3016739	GAASK 10X10 12L XRAY *S* PIP10	IIa	7
13-705	115020	3016740	GAASK 10X20 12L XRAY *S* PIP5	IIa	7
13-705	115021	3016741	GAASK 10X20 12L XRAY *S* PIP10	IIa	7
13-705	115023	3016742	GAASK 10X20 24L XRAY *S* PIP5	IIa	7
13-705	115046	3016744	GAASK 20X25 16L XRAY *S* PIP5	IIa	7
13-705	115048	3016746	GAASK 20X25 32L XRAY *S* PIP2	IIa	7
13-705	115050	3016747	BUIKGAAS 45X30CM 4L X-RAY *S*	IIa	7
13-705	115062	3016749	BUIKGAAS 45X45CM 4L X-RAY *S*	IIa	7
13-705	115064	3016751	BUIKGAAS 45X45CM 4L X-RAY LUS *S	IIa	7
13-705	115060	3016748	BUIKGAAS 45X70CM 4L X-RAY *S*	IIa	7
13-705	115063	3016750	BUIKGAAS 45X70CM 4L X-RAY *S*	IIa	7
13-705	115065	3016752	BUIKGAAS 45X70CM 4L X-RAY *S*	IIa	7
13-705	115075	3016754	BUIKGAAS 45X70CM 4L X-RAY *S*	IIa	7
13-705	115076	3016755	GAASDEPPER NR2 X-RAY *S*	IIa	7
13-705	115077	3016756	GAASDEPPER NR3 X-RAY *S*	IIa	7
13-705	115078	3016757	GAASDEPPER NR4 X-RAY *S*	IIa	7
13-705	115079	3016758	GAASDEPPER NR5 X-RAY *S*	IIa	7
13-705	115100	3016760	PREP TUPFER 6X 6CM X-RAY *S*	IIa	7
13-705	115101	3016761	PREP TUPFER 8X 8CM X-RAY *S*	IIa	7
13-705	115102	3016762	PREP TUPFER 12X12CM X-RAY *S*	IIa	7
10-966	170901	3016984	JOJO'S KLINION *S*	IIa	7
13-705	115601	3016769	NW COMPR 10X10 X-RAY 5X20 *S*	IIa	7
13-705	115611	3016770	NW COMPR 45X45 4L X-RAY *S*	IIa	7
10-966	111001	3016679	KOMPRES HG 8,5X5 8L *S* 16X1	Is	4
10-966	111002	3016680	KOMPRES HG 8,5X5 *S* 100X1	Is	4
10-966	111016	3016685	KOMPRES HG 5X5 12L *S* 10X1	Is	4
10-966	111017	3016686	KOMPRES HG 5X5 12L *S* 100X1	Is	4
10-966	111018	3016687	KOMPRES HG 5X5 12L *S* 50X2	Is	4
10-966	111020	3016689	KOMPRES HG 5X5 12L *S* 20X5	Is	4
10-966	111022	3016691	KOMPRES HG 7,5x7.5cm *S*12ply	Is	4
10-966	111082	3016705	KOMPRES HG 10X10 8L *S* 100X1	Is	4
10-966	111084	3016706	KOMPRES HG 10X10 12L *S* 25X1	Is	4
10-966	111085	3016707	KOMPRES HG 10X10 12L *S* 100X1	Is	4
10-966	111086	3016708	KOMPRES HG 10X10 12L *S* 50X2	Is	4
10-966	111088	3016710	KOMPRES HG 10X10 12L *S* 20X5	Is	4
10-966	111112	3016715	KOMPRES HG 10X20 12L *S* 50X1	Is	4
10-966	111113	3016716	KOMPRES HG 10X20 12L *S* 40X2	Is	4
10-966	170115	3016982	SPLITKOMPR 10X10CM *S* KLINION	Is	4
10-966	170116	3016983	HG DRAINCOMPRES 10X10 *S* 25X2	Is	4
10-966	175001	3017044	KOMPRES NW 5X 5CM *S* 100X1ST	Is	4
10-966	175002	3017045	KOMPRES NW 5X 5CM *S* 50X2	Is	4
10-966	175003	3017046	KOMPRES NW 5X 5CM *S* 5ST	Is	4
10-966	175008	3017048	KOMPRES NW 7,5X7,5CM *S* 2ST	Is	4
10-966	175009	3017049	KOMPRES NW 7,5X7,5CM *S* 5ST	Is	4
10-966	175029	3017052	KOMPRES NW 10X10 4L *S* 10X1	Is	4
10-966	175030	3017053	KOMPRES NW 10X10CM *S* 100X1	Is	4
10-966	175031	3017054	KOMPRES NW 10X10CM *S* 50X2	Is	4
10-966	175033	3017055	KOMPRES NW 10X10CM *S* 5ST	Is	4
10-966	175040	3017058	KOMPRES NW 10X20 4L *S* 50X1	Is	4

UMDNS	REF nr	Article nr	Product Name	Class	Rule
10-966	175041	3017059	KOMPRES NW 10X20 4L *S* 25X2	Is	4
10-966	175050	3017062	SPLITKOMPR 5X 5CM *S* KLINION (50x2)	Is	4
10-966	175051	3017063	SPLITKOMPR 10X10CM *S* KLINION (50x2)	Is	4
10-966	175101	3017070	KOMPRES NW 5X5 8L *S* XTR 100X1	Is	4
10-966	175130	3017076	KOMPRES NW 10X10 8L *S* EX 100X1	Is	4
10-966	175131	3017077	KOMPRES NW 10X10 8L *S* EX 50X2	Is	4
10-966	175140	3017079	KOMPRES NW 10X20 8L *S* XTR 50X1	Is	4
10-966	111089	3016711	KOMPRES HG 10X10 12L *S* 10X10	Is	4
10-966	111223	3016724	KOMPRES HG 20X20 16L *S* 30X1	Is	4
10-966	111235	3016725	KOMPRES HG 20X20 8L *S* 10X5	Is	4
10-966	111255	3016726	KOMPRES HG 20X25 16L *S* 25X1	Is	4
10-966	111256	3016727	KOMPRES HG 20X30 16L *S* 20X1	Is	4
13-700	111010	3016682	KOMPRES HG 5X5 *S* 8L 50*2	Is	4
13-700	111015	3016684	KOMPRES HG 5X5 *S* 8L 30X5	Is	4
13-700	111041	3016699	KOMPRES HG7,5X7,5*S* 8L 50*2	Is	4
13-700	111043	3016701	KOMPRES HG7,5X7,5*S* 8L S5.	Is	4
13-700	111080	3016704	KOMPRES HG 10X10 8L *S* 50X2	Is	4
13-700	111078	3016702	KOMPRES HG10X10*S* 8L 30*5	Is	4
13-700	40512070	3016479	KLINIPRESS NW 5X5CM 4P 5PC *S*	Is	4
13-700	40512071	3016480	KLINIPRESS NW 7.5CM 4P 5PC *S*	Is	4
13-700	40512072	3016481	KLINIPRESS NW 10CM 4P 5PC *S*	Is	4
13-700	40512073	3016482	KLINIPRESS NW 10X20 4P 5PC *S*	Is	4
13-700	40512090	3016487	KLINIPRESS HG COMP 5 CM 8P *S*	Is	4
13-700	40512091	3016488	KLINIPRESS HGCOMP 7.5CM 8P *S*	Is	4
13-700	40512092	3016489	KLINIPRESS HG COMP 10CM 8P *S*	Is	4
13-700	40512101	3016492	KLINIPRESS HG 7.5CM 8PL 5PC*S*	Is	4
13-700	170010	3016955	Absorb Verb 10x10 S 50x1	Is	4
13-700	170011	3016956	Absorb Verb 10x20 S 40x1	Is	4
13-700	170012	3016957	Absorb Verb 15x25 S 20x1	Is	4
13-700	170013	3016958	Absorb Verb 20x20 S 20x1	Is	4
13-700	170014	3016959	Absorb Verb 20x30 S 15x1	Is	4
13-700	170015	3016960	Absorb Verb 20x40 S	Is	4
11-325	40175066	3052409	KLINIPRESS ALUPAD TRACHEA 8X10CM	Is	4
11-325	40175064	3052503	KLINIPRESS ALUPAD 10X10CM	Is	4
11-315	170031	3016962	KLINI-AID Emergency dressing 12X12CM *S*	Is	4
11-315	170032	3016963	KLINI-AID Emergency dressing 18X18CM *S*	Is	4
11-315	170033	3016964	KLINI-AID Emergency dressing 18X28CM *S*	Is	4
11-315	40170041	3052510	KLINI-AID Emergency dressing 6X8CM *S	Is	4
10-966	170000	3016950	KLINION EXSUPAD 9X12CM *S*	Is	4
10-966	170002	3016951	KLINION EXSUPAD 10X20CM *S*	Is	4
10-966	170003	3016952	KLINION EXSUPAD 20X20CM *S*	Is	4
10-966	170004	3016953	KLINION EXSUPAD 20X30CM *S*	Is	4
10-966	170005	3016954	KLINION EXSUPAD 20X40CM *S*	Is	4
10-966	175060W	3017064	NOVOPAD 5X 5CM *S*	Is	4
10-966	175061W	3017065	NOVOPAD 10X10CM *S*	Is	4
10-966	175062W	3017066	NOVOPAD 10X20CM *S*	Is	4
17-428	40514840	3016547	Kliniderm Film 4x5cm *S*	Is	4
17-428	40514841	3016548	Kliniderm Film 5x7.2cm *S*	Is	4
17-428	40514842	3016549	Kliniderm Film 10x10cm *S*	Is	4
17-428	40514843	3016550	Kliniderm Film 10x12cm *S*	Is	4
17-428	40514844	3016551	Kliniderm Film 10x15cm *S*	Is	4
17-428	40514845	3016552	Kliniderm Film 10x20cm *S*	Is	4
17-428	40514846	3016553	Kliniderm Film 10x25cm *S*	Is	4
17-428	40514847	3016554	Kliniderm Film 10x30cm *S*	Is	4
17-428	40514848	3016555	Kliniderm Film 15x20cm *S*	Is	4
17-428	40514849	3016556	Kliniderm Film 20x30cm *S*	Is	4
17-428	40514855	3016557	Kliniderm Film IV 6x7cm *S*	Is	4
17-428	40514860	3016558	Kliniderm Film 5x7.2cm with pad *S*	Is	4
17-428	40514861	3016559	Kliniderm Film 10x10cm with pad *S*	Is	4
17-428	40514862	3016560	Kliniderm Film 10x12cm with pad *S*	Is	4
17-428	40514863	3016561	Kliniderm Film 10x15cm with pad *S*	Is	4
17-428	40514864	3016562	Kliniderm Film 10x20cm with pad *S*	Is	4
17-428	40514865	3016563	Kliniderm Film 10x25cm with pad *S*	Is	4

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17-428	40514866	3016564	Kliniderm Film 10x30cm with pad *S*	Is	4
17-428	40514867	3016565	Kliniderm Film 10x35cm with pad *S*	Is	4
17-428	40514868	3016566	Kliniderm Film 15x20cm with pad *S*	Is	4
17-428	40514869	3016567	Kliniderm Film 20x30cm with pad *S*	Is	4
17-428	40174420	3052512	Kliniderm Film IV NONWOVEN	Is	4
10-276	294200	3017120	KLINIPLAST BORDER 5X 7CM *S*	Is	4
10-276	294201	3017121	KLINIPLAST BORDER 8X10CM *S*	Is	4
10-276	294203	3017122	KLINIPLAST BORDER 8X15CM *S*	Is	4
10-276	294204	3017123	KLINIPLAST BORDER 10X20CM *S*	Is	4
10-276	294205	3017124	KLINIPLAST BORDER 10X25CM *S*	Is	4
10-276	294206	3017125	KLINIPLAST BORDER 10X30CM *S*	Is	4
10-276	40294111	3052511	KLINIPLAST BORDER 5X7CM *S*	Is	4
10-276	40514200	3016515	KLINIPLAST ISLAND PLAS 6X7 *S*	Is	4
10-276	40514201	3016516	KLINIPLAST ISLAND PLAS 9X10 *S*	Is	4
10-276	40514202	3016517	KLINIPLAST ISLAND PLAS 9X15 *S*	Is	4
10-276	40514203	3016518	KLINIPLAST ISLAND PLAS 9X20 *S	Is	4
10-276	40514204	3016519	KLINIPLAST ISLAND PLAS 9X25 *S	Is	4
10-276	40514205	3016520	KLINIPLAST ISLAND PLAS 9X30 *S	Is	4
10-276	40514206	3035436	KLINIPLAST ISLAND PLAS 9X35 *S	Is	4
17-428	174420	3017013	KLINIDERM FILM IV 8X5,5CM *S*	Is	4
10-276	294111	3017094	KLINIPLAST COMFORT 5X 7CM *S*	Is	4
11-325	175064	3017067	ALUPAD WONDKOMPRES 10X10CM *S*	Is	4
11-325	175065	3017068	ALUPAD WONDKOMPRES 10X15CM *S*	Is	4
11-325	175066	3017069	ALUPAD TRACHEO KOMP 8X10CM *S	Is	4
10-274	170035	3016965	KLINI-AID ROLL SNELV 6X8CM*S	Is	4
10-274	170036	3016966	KLINI-AID ROLL SNELV 8X10CM*S	Is	4
10-274	170037	3016967	KLINI-AID ROLL SNELV 10X12CM*S	Is	4
10-274	170040	3016968	KLINI-AID READY SNELVERB 4X5CM.	Is	4
10-274	170041	3016969	KLINI-AID READY SNELV 8X6CM*S*.	Is	4
10-274	170042	3016970	KLINI-AID READY SNELVRB 8X10CM.	Is	4
13-700	111040	3016698	KOMPRES HG7,5X7,5*S* 8L 100*1	Is	4
13-700	170016	3016961	NW COMPR 7,0X5,2 OOG OPTI *S*	Is	4