

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 : Woundcare and Bandages Class I sterile
Intended purpose :

Product	Intended purpose
Klinipress HG Gauze Compress	Gauze compress for cleansing and covering the wound.
Klinipress Gauze Compress Green	Gauze compress for anaesthesia for cleansing of the skin. Green colour to avoid confusion with operation gauzes.
Klinipress Drain Gauze Compress	Gauze drain sponge for covering entry sites of drains, cannulae and catheters.
Klinipress Nonwoven Compress	Nonwoven swab for cleaning wounds and skin.
Klinipress Drain Compress Nonwoven	Nonwoven swab for covering entry sites of drains, cannulae and catheters.
Kliniderm® Film	Wound film for surface wounds with slight exudate.
Kliniderm® Film with pad	Wound film with absorbent wound pad for surface wounds with slight exudate.
Kliniderm® Film IV/ IV nonwoven	Wound film with opening for securing intravenous cannulas.
Klinipress Alupad	For superficial wounds with light to moderate exudate. The wound contact surface has a non-adherent aluminium layer.
Klinipress Alupad Trachea	For use with a trachea cannula. The wound contact surface has a non-adherent aluminium layer.
Klinipress Novopad	For superficial wounds with little to moderate exudate, with a non-adherent film layer on both sides.
Klinipress Exsupad	For moderately exuding wounds. Wound side – white, External side – blue.
Klinipress Absorbent Wound Dressing	For moderately exuding wounds. Wound side – white, External side – blue.

Klinion® Klini-Aid	Rapidly cover a bleeding wound.
Kliniplast Border	Cover dry wounds or wounds with low exudation.
Kliniplast Border Waterproof	Cover dry wounds or wounds with low exudation.

- 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

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

CE certificate : MDR 754472
First Issue Date certificate : 25-04-2024
Validity : 24-04-2029

UK Approved Body : BSI Assurance UK Ltd., Approved Body Number 0086,
Kitemark Court, Davy Avenue,
Milton Keynes MK 8PP,
United Kingdom

UKCA certificate : UKCA 753332
First Issue Date certificate : 20-08-2021
Validity : 16-04-2025

UK Responsible Person : H&R Healthcare Ltd.,
UKRP address : 3 Redcliff Road Melton Park, Melton Hull HU 14 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, 23-09-2024

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

Signature :



Product list related to DoC_753332_W1s

Ref Nr	Article_Description_QA	Class	Rule_MDR	BASIC_UDI-DI
111010	KOMPRES HG 5X5 *S* 8L 50*2	Is	4	18756KLHGM0201LL
111015	KOMPRES HG 5X5 *S* 8L 30X5	Is	4	18756KLHGM0201LL
111018	KOMPRES HG 5X5 12L *S* 50X2	Is	4	18756KLHGM0201LL
111020	KOMPRES HG 5X5 12L *S* 20X5	Is	4	18756KLHGM0201LL
111022	KOMPRES HG 7,5x7.5cm *S*12ply	Is	4	18756KLHGM0201LL
111041	KOMPRES HG7,5X7,5*S* 8L 50*2	Is	4	18756KLHGM0201LL
111043	KOMPRES HG7,5X7,5*S* 8L S5.	Is	4	18756KLHGM0201LL
111078	KOMPRES HG10X10*S* 8L 30*5	Is	4	18756KLHGM0201LL
111080	KOMPRES HG 10X10 8L *S* 50X2	Is	4	18756KLHGM0201LL
111086	KOMPRES HG 10X10 12L *S* 50X2	Is	4	18756KLHGM0201LL
111088	KOMPRES HG 10X10 12L *S* 20X5	Is	4	18756KLHGM0201LL
111089	KOMPRES HG 10X10 12L *S* 10X10	Is	4	18756KLHGM0201LL
111113	KOMPRES HG 10X20 12L *S* 40X2	Is	4	18756KLHGM0201LL
111235	KOMPRES HG 20X20 8L *S* 10X5	Is	4	18756KLHGM0201LL
111255	KOMPRES HG 20X25 16L *S* 25X1	Is	4	18756KLHGM0201LL
170000	KLINION EXSUPAD 9X12CM *S*	Is	4	18756KLADM040204SY
170002	KLINION EXSUPAD 10X20CM *S*	Is	4	18756KLADM040204SY
170003	KLINION EXSUPAD 20X20CM *S*	Is	4	18756KLADM040204SY
170004	KLINION EXSUPAD 20X30CM *S*	Is	4	18756KLADM040204SY
170005	KLINION EXSUPAD 20X40CM *S*	Is	4	18756KLADM040204SY
170010	Absorb Verb 10x10 S 50x1	Is	4	18756KLADM040204SY
170011	Absorb Verb 10x20 S 40x1	Is	4	18756KLADM040204SY
170012	Absorb Verb 15x25 S 20x1	Is	4	18756KLADM040204SY
170013	Absorb Verb 20x20 S 20x1	Is	4	18756KLADM040204SY
170014	Absorb Verb 20x30 S 15x1	Is	4	18756KLADM040204SY
170015	Absorb Verb 20x40 S	Is	4	18756KLADM040204SY
170031	KLINI-AID Emergency dressing 12X12CM *S*	Is	4	18756KLADM040204SY
170032	KLINI-AID Emergency dressing 18X18CM *S*	Is	4	18756KLADM040204SY

170033	KLINI-AID Emergency dressing 18X28CM *S*	Is	4	18756KLADM040204SY
170115	SPLITKOMPR 10X10CM *S* KLINION	Is	4	18756KLHGM0201LL
170116	HG DRAINCOMPRES 10X10 *S* 25X2	Is	4	18756KLHGM0201LL
175001	KOMPRES NW 5X 5CM *S* 100X1ST	Is	4	18756KLPNWM0202F4
175002	KOMPRES NW 5X 5CM *S* 50X2	Is	4	18756KLPNWM0202F4
175003	KOMPRES NW 5X 5CM *S* 5ST	Is	4	18756KLPNWM0202F4
175008	KOMPRES NW 7,5X7,5CM *S* 2ST	Is	4	18756KLPNWM0202F4
175009	KOMPRES NW 7,5X7,5CM *S* 5ST	Is	4	18756KLPNWM0202F4
175030	KOMPRES NW 10X10CM *S* 100X1	Is	4	18756KLPNWM0202F4
175031	KOMPRES NW 10X10CM *S* 50X2	Is	4	18756KLPNWM0202F4
175033	KOMPRES NW 10X10CM *S* 5ST	Is	4	18756KLPNWM0202F4
175040	KOMPRES NW 10X20 4L *S* 50X1	Is	4	18756KLPNWM0202F4
175050	SPLITKOMPR 5X 5CM *S* KLINION (50x2)	Is	4	18756KLHGM0201LL
175051	SPLITKOMPR 10X10CM *S* KLINION (50x2)	Is	4	18756KLHGM0201LL
294200	KLINIPLAST BORDER 5X 7CM *S*	Is	4	18756KLPLM040101A9
294201	KLINIPLAST BORDER 8X10CM *S*	Is	4	18756KLPLM040101A9
294203	KLINIPLAST BORDER 8X15CM *S*	Is	4	18756KLPLM040101A9
294204	KLINIPLAST BORDER 10X20CM *S*	Is	4	18756KLPLM040101A9
294205	KLINIPLAST BORDER 10X25CM *S*	Is	4	18756KLPLM040101A9
294206	KLINIPLAST BORDER 10X30CM *S*	Is	4	18756KLPLM040101A9
40170041	KLINI-AID Emergency dressing 6X8CM *S	Is	4	18756KLADM040204SY
40174420	Kliniderm Film IV NONWOVEN	Is	4	18756KLFLM0401MV
40175064	KLINIPRESS ALUPAD 10X10CM	Is	4	18756KLADM040204SY
40175066	KLINIPRESS ALUPAD TRACHEA 8X10CM	Is	4	18756KLADM040204SY
40294111	KLINIPLAST BORDER 5X7CM *S*	Is	4	18756KLPLM040101A9
40512070	KLINIPRESS NW 5X5CM 4P 5PC *S*	Is	4	18756KLPNWM0202F4
40512071	KLINIPRESS NW 7.5CM 4P 5PC *S*	Is	4	18756KLPNWM0202F4
40512072	KLINIPRESS NW 10CM 4P 5PC *S*	Is	4	18756KLPNWM0202F4
40514200	KLINIPLAST ISLAND PLAS 6X7 *S*	Is	4	18756KLPLM040101A9
40514201	KLINIPLAST ISLAND PLAS 9X10 *S*	Is	4	18756KLPLM040101A9
40514202	KLINIPLAST ISLAND PLAS 9X15 *S*	Is	4	18756KLPLM040101A9

40514203	KLINIPLAST ISLAND PLAS 9X20 *S	Is	4	18756KLPLM040101A9
40514204	KLINIPLAST ISLAND PLAS 9X25 *S	Is	4	18756KLPLM040101A9
40514205	KLINIPLAST ISLAND PLAS 9X30 *S	Is	4	18756KLPLM040101A9
40514206	KLINIPLAST ISLAND PLAS 9X35 *S	Is	4	18756KLPLM040101A9
40514840	Kliniderm Film 4x5cm *S*	Is	4	18756KLFDMM040406WZ
40514841	Kliniderm Film 5x7.2cm *S*	Is	4	18756KLFDMM040406WZ
40514842	Kliniderm Film 10x10cm *S*	Is	4	18756KLFDMM040406WZ
40514843	Kliniderm Film 10x12cm *S*	Is	4	18756KLFDMM040406WZ
40514844	Kliniderm Film 10x15cm *S*	Is	4	18756KLFDMM040406WZ
40514845	Kliniderm Film 10x20cm *S*	Is	4	18756KLFDMM040406WZ
40514846	Kliniderm Film 10x25cm *S*	Is	4	18756KLFDMM040406WZ
40514847	Kliniderm Film 10x30cm *S*	Is	4	18756KLFDMM040406WZ
40514848	Kliniderm Film 15x20cm *S*	Is	4	18756KLFDMM040406WZ
40514849	Kliniderm Film 20x30cm *S*	Is	4	18756KLFDMM040406WZ
40514855	Kliniderm Film IV 6x7cm *S*	Is	4	18756KLPLM040101A9
40514860	Kliniderm Film 5x7.2cm with pad *S*	Is	4	18756KLFDMM040406WZ
40514861	Kliniderm Film 10x10cm with pad *S*	Is	4	18756KLFDMM040406WZ
40514862	Kliniderm Film 10x12cm with pad *S*	Is	4	18756KLFDMM040406WZ
40514863	Kliniderm Film 10x15cm with pad *S*	Is	4	18756KLFDMM040406WZ
40514864	Kliniderm Film 10x20cm with pad *S*	Is	4	18756KLFDMM040406WZ
40514865	Kliniderm Film 10x25cm with pad *S*	Is	4	18756KLFDMM040406WZ
40514866	Kliniderm Film 10x30cm with pad *S*	Is	4	18756KLFDMM040406WZ
40514867	Kliniderm Film 10x35cm with pad *S*	Is	4	18756KLFDMM040406WZ
40514868	Kliniderm Film 15x20cm with pad *S*	Is	4	18756KLFDMM040406WZ
175060W	NOVOPAD 5X 5CM *S*	Is	4	18756KLADM040204SY
175061W	NOVOPAD 10X10CM *S*	Is	4	18756KLADM040204SY
175062W	NOVOPAD 10X20CM *S*	Is	4	18756KLADM040204SY