

9Manufacturer's Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Issuer's name	.	Medeco Gloves Chamber of Commerce Registration # 23038479
Issuer's address	..	Alexander Flemingstraat 2 3261 MA Oud Beijerland The Netherlands
Object of the declaration	..	General Supplies (MDD)
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.

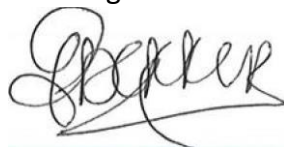
This documentation is supported by the Quality Management System certification based on the harmonized standard EN ISOM 3485:2016, Quality ManagementSystem Certificate with reference numbers: MD 644507, issued for the 1st time on 20 June 2016, and delivered by BSI

UK. The applied standards for this family of products is maintained in the Technical Dossier.

Oud Beijerland, 6 February 2019

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

Signature



Doc MDD Class I General Supplies
Rev. 03

FRM 423-10
Rev. 4/19.02.06

Product list related to DOC MD Class I - General Supplies

REF nr	Article nr	Description		Class	Rule
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130112	3016779	Klinion Cold Compress Instant1	130113	3016780	Klinion Cold Hot Compress S1		
130115	3016781	Klinion Cold Hot Compress L					
590603	3026178				Klinion Tray 225x135x20mm1		
690101	3048924				Klinion Kidney Tray 750 ml1		
531510	3025578				Cotton Swabs Naket Medispo5		
531520	3025579				Cotton Swabs Plastic 15 cm Big Ball Medispo5		
531530	3025580				Cotton Swabs Wood 15 cm Small Ball Medispo5		
531540	3025582				Cotton Swabs Plastic 7.5 cm Small Ball both sides Medispo5		
77510301	3028325	Tongue Spatula Wood5					
77510302	3028326	Tongue Spatula Child5					
522100	3025534				Klinion Glove PE Smooth1		
522102	3025535	Klinion Glove PE Embossed					
522220	3025543				Klinion Visitor Gown NW Snap Front Buttons1		
522210	3025542				Klinion Isolation Gown NW Blue1		
522230	3025544	Klinion Isolation Gown NW Yellow					1
1921-00	3037026				Klinion Isolation Gown NW Yellow XL1		
522240	3025547				Klinion Isolation Gown NW/CPE Yellow M1		
522250	3025550				Klinion Isolation Gown NW/CPE Yellow L1		
522310	3025552				Klinion Bouffant Crimp Cap Blue1		
522320	3025553				Klinion Bouffant Crimp Cap White1		
522330	3025554				Klinion Bouffant Crimp Cap Green1		
522610	3025563	Klinion Shoe Cover CPE Blue					1
522620	3025564	Klinion Shoe Cover NW Blue					1
703073	3026979	Klinion Shorts X-ray Disposable		104 cm			1
				134 cm			1
				h 144 cm			1
741244	3027534	Klinion Impervious gown yellow M Length		cm			1
104 cm	1			cm			1
741243	3027533	Klinion Impervious gown yellow L Length		and velcro M Length 115 cm			1
134 cm	1			and velcro L Length 134 cm			1
702100	3026974	Klinion Impervious gown yellow X-L Length		and velcro XL Length 142 cm			1
144 cm	1			cm M			1
				cm XL			1
741251	3027535	Klinion Isolation gown blue M					1,5
		Length 115 cm	1				1,5
741252	3027536	Klinion Isolation gown blue XL					1,5
		Length 144 cm	1				1,5
702101	3026975	Klinion Isolation gown regular blue w/cuff		sleeve 300 mm S, with tape			1,5
and velcro M Length 115 cm	1			sleeve 300 mm M, with tape			1,5
706144	3026989	Klinion Isolation gown regular blue		sleeve 300 mm L, with tape			1,5
				sleeve 300 mm XL, with tape			1,5
		w/cuff and velcro L Length 134 cm	1				1,5
706145	3038998	Klinion Isolation gown regular blue					1,5
		w/cuff and velcro XL Length 142 cm	1				1,5
71429	3027102	Klinion Protection gown SMS Purple		- long cuff			1,5
125 cm M	1			long cuff			1,5
71430	3027103	Klinion Protection gown SMS Purple		long cuff			1,5
145 cm XL	1			long cuff			1,5
102420	3016629	Vinyl examination glove powder free XS		- long cuff			1,5
102425	3016630	Vinyl examination glove powder free S					
102426	3016631	Vinyl examination glove powder free M					
102427	3016632	Vinyl examination glove powder free L					
102428	3016633	Vinyl examination glove powder free XL					
165030	3016946	Vinyl examination glove powder free long sleeve 300 mm S, with tape					
165031	3016947	Vinyl examination glove powder free long sleeve 300 mm M, with tape					
165032	3016948	Vinyl examination glove powder free long sleeve 300 mm L, with tape	165033	3039690	Vinyl examination glove powder free long sleeve 300 mm XL, with tape		
75685220	-3037665	Vin examination loves Phtalate free XS					
75685221	3037669	Vinyl examination gloves Phtalate free S					
75685222	3037692	Vinyl examination gloves Phtalate free M					

75685223	3037694	Vinyl examination gloves Phtalate free L
75685224	3037696	Vinyl examination gloves Phtalate free XL
75685129	3037698	Vinyl examination gloves Phtalate free XS - long cuff
75685130	3037710	Vinyl examination gloves Phtalate free S - long cuff
75685131	3037711	Vinyl examination gloves Phtalate free M - long cuff
75685132	3037712	Vinyl examination gloves Phtalate free L - long cuff
75685133	3037714	Vinyl examination gloves Phtalate free XL - long cuff

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