



A MEDIQ COMPANY

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** : MD General supplies
- 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, 26 April 2021

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

Signature :

Product list related to DoC MD Class I – General Supplies

Ref Nr	Article Description	Class	Rule	BASIC UDI-DI
102420	Vinyl examination glove powder free XS	I	1	18756KPPT0102N6
102425	Vinyl examination glove powder free S	I	1	18756KPPT0102N6
102426	Vinyl examination glove powder free M	I	1	18756KPPT0102N6
102427	Vinyl examination glove powder free L	I	1	18756KPPT0102N6
102428	Vinyl examination glove powder free XL	I	1	18756KPPT0102N6
165030	Vinyl examination glove powder free long sleeve 300 mm S, with tape	I	1	18756KPPT0102N6
165031	Vinyl examination glove powder free long sleeve 300 mm M, with tape	I	1	18756KPPT0102N6
165032	Vinyl examination glove powder free long sleeve 300 mm L, with tape	I	1	18756KPPT0102N6
522100	Klinion Glove PE Smooth	I	1	18756KPPT0102N6
522102	Klinion Glove PE Embossed	I	1	18756KPPT0102N6
522210	Klinion Isolation Gown NW Blue	I	1	18756KPPT0205NH
522220	Klinion Visitor Gown NW Snap Front Buttons	I	1	18756KPPT0205NH
522230	Klinion Isolation Gown NW Yellow	I	1	18756KPPT0205NH
522240	Klinion Isolation Gown NW/CPE Yellow M	I	1	18756KPPT0205NH
522250	Klinion Isolation Gown NW/CPE Yellow L	I	1	18756KPPT0205NH
522310	Klinion Bouffant Crimp Cap Blue	I	1	18756KLCOT0207PY
522320	Klinion Bouffant Crimp Cap White	I	1	18756KLCOT0207PY
522330	Klinion Bouffant Crimp Cap Green	I	1	18756KLCOT0207PY
522610	Klinion Shoe Cover CPE Blue	I	1	18756KLCOT0208Q2
522620	Klinion Shoe Cover NW Blue	I	1	18756KLCOT0208Q2
702100	Klinion Impervious gown yellow X-L Length 144 cm	I	1	18756KPPT0205NH
702101	Klinion Isolation gown regular blue w/cuff and velcro M Length 114 cm	I	1	18756KPPT0205NH
703073	Klinion Shorts X-ray Disposable	I	1	18756KPPT0299PL
706144	Klinion Isolation gown regular blue w/cuff and velcro L Length 134 cm	I	1	18756KPPT0205NH
741243	Klinion Impervious gown yellow L Length 134 cm	I	1	18756KPPT0205NH
741244	Klinion Impervious gown yellow M Length 114 cm	I	1	18756KPPT0205NH
741251	Klinion Isolation gown blue M Length 114 cm	I	1	18756KPPT0205NH

Product list related to DoC MD Class I – General Supplies

Ref Nr	Article Description	Class	Rule	BASIC UDI-DI
741252	Klinion Isolation gown blue XL Length 144 cm	I	1	18756KPPT0205NH
1921-00	Klinion Isolation Gown NW Yellow XL	I	1	18756INCCT0401JS
75685220	Vinyl examination gloves Phtalate free XS	I	1	18756KPPT0102N6
75685221	Vinyl examination gloves Phtalate free S	I	1	18756KPPT0102N6
75685222	Vinyl examination gloves Phtalate free M	I	1	18756KPPT0102N6
75685223	Vinyl examination gloves Phtalate free L	I	1	18756KPPT0102N6
75685224	Vinyl examination gloves Phtalate free XL	I	1	18756KPPT0102N6
75685129	Vinyl examination gloves Phtalate free XS - long cuff	I	1	18756KPPT0102N6
75685130	Vinyl examination gloves Phtalate free S - long cuff	I	1	18756KPPT0102N6
75685131	Vinyl examination gloves Phtalate free M - long cuff	I	1	18756KPPT0102N6
75685132	Vinyl examination gloves Phtalate free L - long cuff	I	1	18756KPPT0102N6
75685133	Vinyl examination gloves Phtalate free XL - long cuff	I	1	18756KPPT0102N6
706145	Klinion Isolation gown regular blue w/cuff and velcro XL Length 142 cm	I	1	18756KPPT0205NH
165033	Vinyl examination glove powder free long sleeve 300 mm XL, with tape	I	1	18756KPPT0102N6
7412441	Klinion Impervious gown blue L Length 120 cm	I	1	18756KPPT0205NH