

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	:	Latex gloves
Single registration number	:	NL-MF-000001628
Classification	:	REGULATION (EU) 2017/745 Annex VIII, see attached Product list PPE Category I
Conformity assessment	:	REGULATION (EU) 2017/745 Annex II and Annex III PPE: EU Type Examination, Module A
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
- PPE (EU) 2016/425: Regulation (EU) 2016/425 of March 2016 on personal protective equipment


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, 11 May 2021

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

Signature :



Product list related to DoC MD Class I and PPE – Latex Gloves

Ref Nr	Article Description	Class	Rule	Category PPE	BASIC UDI-DI
102315	PREPOWDERED LATEX EXAM GLOVE S	I	1	I	18756KPPT0102N6
102316	PREPOWDERED LATEX EXAM GLOVE M	I	1	I	18756KPPT0102N6
102317	PREPOWDERED LATEX EXAM GLOVE L	I	1	I	18756KPPT0102N6
102318	PREPOWDERED LATEX EXAM GLOVE XL	I	1	I	18756KPPT0102N6
102645	POLYMER COATED Powder Free LATEX EXAM GLOVE XS	I	1	I	18756KPPT0102N6
102646	POLYMER COATED Powder Free LATEX EXAM GLOVE S	I	1	I	18756KPPT0102N6
102647	POLYMER COATED Powder Free LATEX EXAM GLOVE M	I	1	I	18756KPPT0102N6
102648	POLYMER COATED Powder Free LATEX EXAM GLOVE L	I	1	I	18756KPPT0102N6
102649	POLYMER COATED Powder Free LATEX EXAM GLOVE XL	I	1	I	18756KPPT0102N6
7551545	CHLORINATED Powder Free LATEX EXAM GLOVE XS	I	1	I	18756KPPT0102N6
102650	KPP CHLORINATED PF LATEX EXAM GLOVE XS	I	1	I	18756KPPT0102N6
102651	KPP CHLORINATED PF LATEX EXAM GLOVE S	I	1	I	18756KPPT0102N6
102652	KPP CHLORINATED PF LATEX EXAM GLOVE M	I	1	I	18756KPPT0102N6
102653	KPP CHLORINATED PF LATEX EXAM GLOVE L	I	1	I	18756KPPT0102N6
102654	KPP CHLORINATED PF LATEX EXAM GLOVE XL	I	1	I	18756KPPT0102N6