

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 : Nitrile gloves

Single registration number: NL-MF-000001628

Classification : REGULATION (EU) 2017/745 Annex VIII, see attached
Product list
PPE Category III

Conformity assessment : REGULATION (EU) 2017/745 Annex II and Annex III
PPE: EU Type Examination, Module B with Module C2 / D

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, 29 April 2021

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

Signature :



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

Ref Nr	Article Description	Class	Rule	Category PPE	BASIC UDI-DI
102484	SENSITIVE NITRILE EXAM GLOVE - Long S INDIGO	I	1	III	18756KPPT0102N6
102485	SENSITIVE NITRILE EXAM GLOVE - Long M INDIGO	I	1	III	18756KPPT0102N6
102486	SENSITIVE NITRILE EXAM GLOVE - Long L INDIGO	I	1	III	18756KPPT0102N6
102487	SENSITIVE NITRILE EXAM GLOVE - Long XL INDIGO	I	1	III	18756KPPT0102N6
102470	SENSITIVE NITRILE EXAM GLOVE - Long XS INDIGO	I	1	III	18756KPPT0102N6
102471	SENSITIVE NITRILE EXAM GLOVE - Long S INDIGO	I	1	III	18756KPPT0102N6
102472	SENSITIVE NITRILE EXAM GLOVE - Long M INDIGO	I	1	III	18756KPPT0102N6
102473	SENSITIVE NITRILE EXAM GLOVE - Long L INDIGO	I	1	III	18756KPPT0102N6
102474	SENSITIVE NITRILE EXAM GLOVE - Long XL INDIGO	I	1	III	18756KPPT0102N6
102534	SENSITIVE NITRILE EXAM GLOVE XS-L BLUE	I	1	III	18756KPPT0102N6
102535	SENSITIVE NITRILE EXAM GLOVE S-L BLUE	I	1	III	18756KPPT0102N6
102536	SENSITIVE NITRILE EXAM GLOVE M-L BLUE	I	1	III	18756KPPT0102N6
102537	SENSITIVE NITRILE EXAM GLOVE L-L BLUE	I	1	III	18756KPPT0102N6
102538	SENSITIVE NITRILE EXAM GLOVE XL -L BLUE	I	1	III	18756KPPT0102N6
165140	SENSITIVE ULTRA SAFE NITRILE EXAM GLOVE - Long XS BLUE	I	1	III	18756KPPT0102N6
165141	SENSITIVE ULTRA SAFE NITRILE EXAM GLOVE - Long S BLUE	I	1	III	18756KPPT0102N6
165142	SENSITIVE ULTRA SAFE NITRILE EXAM GLOVE - Long M BLUE	I	1	III	18756KPPT0102N6
165143	SENSITIVE ULTRA SAFE NITRILE EXAM GLOVE - Long L BLUE	I	1	III	18756KPPT0102N6
165144	SENSITIVE ULTRA SAFE NITRILE EXAM GLOVE - Long XL BLUE	I	1	III	18756KPPT0102N6
102606	ULTRA COMFORT NITRILE EXAM GLOVE XS BLUE	I	1	III	18756KPPT0102N6
102607	ULTRA COMFORT NITRILE EXAM GLOVE S BLUE	I	1	III	18756KPPT0102N6
102608	ULTRA COMFORT NITRILE EXAM GLOVE M BLUE	I	1	III	18756KPPT0102N6
102609	ULTRA COMFORT NITRILE EXAM GLOVE L BLUE	I	1	III	18756KPPT0102N6
102610	ULTRA COMFORT NITRILE EXAM GLOVE XL BLUE	I	1	III	18756KPPT0102N6
102601	ULTRA COMFORT NITRILE EXAM GLOVE XS WHITE	I	1	III	18756KPPT0102N6
102602	ULTRA COMFORT NITRILE EXAM GLOVE S WHITE	I	1	III	18756KPPT0102N6
102603	ULTRA COMFORT NITRILE EXAM GLOVE M WHITE	I	1	III	18756KPPT0102N6

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

Ref Nr	Article Description	Class	Rule	Category PPE	BASIC UDI-DI
102604	ULTRA COMFORT NITRILE EXAM GLOVE L WHITE	I	1	III	18756KPPT0102N6
102605	ULTRA COMFORT NITRILE EXAM GLOVE XL WHITE	I	1	III	18756KPPT0102N6
165040	ULTRA SAFE NITRILE EXAM GLOVE XS BLUE 4.6	I	1	III	18756KPPT0102N6
165041	ULTRA SAFE NITRILE EXAM GLOVE S BLUE 4.6	I	1	III	18756KPPT0102N6
165042	ULTRA SAFE NITRILE EXAM GLOVE M BLUE 4.6	I	1	III	18756KPPT0102N6
165043	ULTRA SAFE NITRILE EXAM GLOVE L BLUE 4.6	I	1	III	18756KPPT0102N6
165044	ULTRA SAFE NITRILE EXAM GLOVE XL BLUE 4.6	I	1	III	18756KPPT0102N6
102520	ULTRA SAFE NITRILE EXAM GLOVE XS BLUE 3.8	I	1	III	18756KPPT0102N6
102521	ULTRA SAFE NITRILE EXAM GLOVE S BLUE 3.8	I	1	III	18756KPPT0102N6
102522	ULTRA SAFE NITRILE EXAM GLOVE M BLUE 3.8	I	1	III	18756KPPT0102N6
102523	ULTRA SAFE NITRILE EXAM GLOVE L BLUE 3.8	I	1	III	18756KPPT0102N6
102524	ULTRA SAFE NITRILE EXAM GLOVE XL BLUE 3.8	I	1	III	18756KPPT0102N6
102488	SENSITIVE NITRILE EXAM GLOVE - Long XS INDIGO	I	1	III	18756KPPT0102N6