

Manufacturer's 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
- Classification** : PPE Category III
MDD Class I
- Conformity assessment** : PPE: EU Type Examination, Module B with Module C2 / D
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

- PPE (EU) 2016/425: Regulation (EU) 2016/425 of March 2016 on personal protective equipment
- MDD 93/42/EEC: Council Directive 93/42/EEC concerning medical devices June 14th, 1993 as amended by directive 2007/47/EC

and complies 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.

Additional information

Klinion Nitrile Gloves – Ultra:

Notified Body responsible for EU type-examination (Module B) and for conformity assessment procedure (Module C2):

- SATRA Technology Centre Ltd (Notified Body number 0321)
Wyndham Way, Kettering NN16 8SD, UK.
- EU type-examination certificate 0321/10015-02/E06-1, expiry date 21/04/2023

Klinion Nitrile Gloves – Sensitive:

Notified Body responsible for EU type-examination (Module B):

- SATRA Technology Centre Ltd (Notified Body number 0321),
Wyndham Way, Kettering NN16 8SD, UK.
- EU type-examination certificate: 0321/10013-02/E08-1, expiry date 21/04/2023

Notified Body responsible for conformity assessment procedure (Module D):

- SGS United Kingdom Limited (Notified Body number 0120)
Unit 202B Worle Parkway Weston-Super-Mare, Somerset BS22 6WA, UK.

This documentation is supported by the Quality Management System EN ISO 13485:2016 (certificate number MD 644507, effective date 20/06/2016) and ISO 9001:2015 (certificate number FM 644506, effective date 02/02/2016) issued 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 :



Product list related to DoC MD and PPE Nitrile gloves

Article	SAP#	Name	Category PPE	Class	Rule
102488	3051843	SENSITIVE NITRILE EXAM GLOVE - Long XS INDIGO	III	I	1,5
102484	3050618	SENSITIVE NITRILE EXAM GLOVE - Long S INDIGO	III	I	1,5
102485	3050655	SENSITIVE NITRILE EXAM GLOVE - Long M INDIGO	III	I	1,5
102486	3050656	SENSITIVE NITRILE EXAM GLOVE - Long L INDIGO	III	I	1,5
102487	3050657	SENSITIVE NITRILE EXAM GLOVE - Long XL INDIGO	III	I	1,5
102470	3050658	SENSITIVE NITRILE EXAM GLOVE - Long XS INDIGO	III	I	1,5
102471	3050659	SENSITIVE NITRILE EXAM GLOVE - Long S INDIGO	III	I	1,5
102472	3050671	SENSITIVE NITRILE EXAM GLOVE - Long M INDIGO	III	I	1,5
102473	3050673	SENSITIVE NITRILE EXAM GLOVE - Long L INDIGO	III	I	1,5
102474	3050674	SENSITIVE NITRILE EXAM GLOVE - Long XL INDIGO	III	I	1,5
102534	3050697	SENSITIVE NITRILE EXAM GLOVE XS-L BLUE	III	I	1,5
102535	3050698	SENSITIVE NITRILE EXAM GLOVE S-L BLUE	III	I	1,5
102536	3050699	SENSITIVE NITRILE EXAM GLOVE M-L BLUE	III	I	1,5
102537	3050700	SENSITIVE NITRILE EXAM GLOVE L-L BLUE	III	I	1,5
102538	3050701	SENSITIVE NITRILE EXAM GLOVE XL -L BLUE	III	I	1,5
165140	3050866	SENSITIVE ULTRA SAFE NITRILE EXAM GLOVE - Long XS BLUE	III	I	1,5
165141	3050867	SENSITIVE ULTRA SAFE NITRILE EXAM GLOVE - Long S BLUE	III	I	1,5
165142	3050868	SENSITIVE ULTRA SAFE NITRILE EXAM GLOVE - Long M BLUE	III	I	1,5
165143	3050869	SENSITIVE ULTRA SAFE NITRILE EXAM GLOVE - Long L BLUE	III	I	1,5
165144	3050880	SENSITIVE ULTRA SAFE NITRILE EXAM GLOVE - Long XL BLUE	III	I	1,5
102606	3050882	ULTRA COMFORT NITRILE EXAM GLOVE XS BLUE	III	I	1,5
102607	3050883	ULTRA COMFORT NITRILE EXAM GLOVE S BLUE	III	I	1,5
102608	3050884	ULTRA COMFORT NITRILE EXAM GLOVE M BLUE	III	I	1,5
102609	3050885	ULTRA COMFORT NITRILE EXAM GLOVE L BLUE	III	I	1,5
102610	3050886	ULTRA COMFORT NITRILE EXAM GLOVE XL BLUE	III	I	1,5
102601	3050887	ULTRA COMFORT NITRILE EXAM GLOVE XS WHITE	III	I	1,5
102602	3050888	ULTRA COMFORT NITRILE EXAM GLOVE S WHITE	III	I	1,5
102603	3050889	ULTRA COMFORT NITRILE EXAM GLOVE M WHITE	III	I	1,5
102604	3050890	ULTRA COMFORT NITRILE EXAM GLOVE L WHITE	III	I	1,5
102605	3050891	ULTRA COMFORT NITRILE EXAM GLOVE XL WHITE	III	I	1,5
165040	3050934	ULTRA SAFE NITRILE EXAM GLOVE XS BLUE 4.6	III	I	1,5
165041	3050935	ULTRA SAFE NITRILE EXAM GLOVE S BLUE 4.6	III	I	1,5
165042	3050936	ULTRA SAFE NITRILE EXAM GLOVE M BLUE 4.6	III	I	1,5
165043	3050937	ULTRA SAFE NITRILE EXAM GLOVE L BLUE 4.6	III	I	1,5
165044	3050938	ULTRA SAFE NITRILE EXAM GLOVE XL BLUE 4.6	III	I	1,5
102520	3051429	ULTRA SAFE NITRILE EXAM GLOVE XS BLUE 3.8	III	I	1,5
102521	3051430	ULTRA SAFE NITRILE EXAM GLOVE S BLUE 3.8	III	I	1,5
102522	3051431	ULTRA SAFE NITRILE EXAM GLOVE M BLUE 3.8	III	I	1,5
102523	3051432	ULTRA SAFE NITRILE EXAM GLOVE L BLUE 3.8	III	I	1,5
102524	3051433	ULTRA SAFE NITRILE EXAM GLOVE XL BLUE 3.8	III	I	1,5

6/2/19
