

## 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** : Latex Gloves

**Classification** : PPE Category I  
MDD Class I

**Conformity assessment** : PPE: EU Type Examination, Module A  
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.

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 Latex Gloves

Article	SAP#	Name	Category PPE	Class	Rule
102315	3051434	PREPOWDERED LATEX EXAM GLOVE S			1,5
102316	3051435	PREPOWDERED LATEX EXAM GLOVE M			1,5
102317	3051436	PREPOWDERED LATEX EXAM GLOVE L			1,5
102318	3051437	PREPOWDERED LATEX EXAM GLOVE XL			1,5
102645	3051438	POLYMER COATED Powder Free LATEX EXAM GLOVE XS			1,5
102646	3051439	POLYMER COATED Powder Free LATEX EXAM GLOVE S			1,5
102647	3051440	POLYMER COATED Powder Free LATEX EXAM GLOVE M			1,5
102648	3051441	POLYMER COATED Powder Free LATEX EXAM GLOVE L			1,5
102649	3051443	POLYMER COATED Powder Free LATEX EXAM GLOVE XL			1,5
7551545	3051444	CHLORINATED Powder Free LATEX EXAM GLOVE XS			1,5
7551546	3051445	CHLORINATED Powder Free LATEX EXAM GLOVE S			1,5
7551547	3051446	CHLORINATED Powder Free LATEX EXAM GLOVE M			1,5
7551548	3051447	CHLORINATED Powder Free LATEX EXAM GLOVE L			1,5
7551549	3051448	CHLORINATED Powder Free LATEX EXAM GLOVE XL			1,5

6/2/19  
