



# **EC Declaration of Conformity**

## **to the 93/42/EEC Medical Device Directive**

### **2016/425 Personal Protective Equipment Regulation**

Neomedic Ltd declare under our sole responsibility that the medical device specified in the Appendix I meets all provisions of the Medical Device Directive 92/42/EEC and all relevant modifying Directives and PPE Regulation 2016/425 (only Nitrile powder-free gloves).

**Manufacturer:** Neomedic Ltd

**Address:** Unti 2, Leavesden Lodge, 1A Leavesden Road  
Watford  
WD4 5FR, United Kingdom

**Device:** Latex (powdered and powder-free) and Nitrile (powder-free, online and offline) gloves

**Device Classification:** Class I under Rule 1

**CE marking first applied:** December 2019

**GMDN code and term:** 47172, Latex examination/treatment glove, non-powdered, non-sterile  
47173, Latex examination/treatment glove, powdered  
56286, Nitrile examination/treatment glove, non-powdered, non-sterile

**Conformity Route:** Annex VII

This Declaration of Conformity is issued on the basis of fulfilment of requirements of Annex I and Annex VII of the Council Directive 93/42/EEC with:



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Unit 2, Leavesden Lodge, 1A Leavesden Road, Watford, WD4 5FR, UK  
Telephone: +44 1923 836379 • Fax: +44 1923 840160 • [marketing@neomedic.co.uk](mailto:marketing@neomedic.co.uk)



- Quality Management System certification to ISO 13485:2016 under the supervision of SGS United Kingdom Ltd, Notified Body number 0120 and the certificate number GB13/90128.
- Availability of technical documentation per Annex VII of the Medical Device Directive 93/42/EEC.

This Declaration of Conformity is also issued on the basis of fulfilment of the requirements of the Personal Protective Equipment Regulation (EU) 2016/425 for Category III (Module D):

- The conformity to type-based on quality assurance of the production process under surveillance of the Notified Body 2777 Satra Technology Europe Ltd.

Directive/Regulations applied:

- Medical Device Directive 93/42/EEC
- Personal Protective Equipment Regulation 2016/425 (only to Nitrile powder-free gloves, not applicable to Latex gloves)

**Standards applied:**

- EN ISO 13485:2016
- EN ISO 14971:2012
- EN 455-1:2000
- EN 455-2:2015
- EN 455-3:2015
- EN 455-4:2009
- EN 16523-1:2015
- ISO 10993-1: 2018
- EN ISO 10993-5:2009
- EN ISO 10993-10:2013
- EN 388:2003
- EN 420:2003 + A1: 2009
- EN ISO 374-1:2016
- EN ISO 374-2:2014
- EN 374-4:2013
- EN ISO 374-5:2016



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- EN ISO 16604:2004
- EN ISO 15223-1:2016
- EN 1041:2008+A1:2013
- ASTM F1671:2013
- ASTM D3578:2019
- ASTM D7160:2016
- ASTM D7161:2016

Authorised signatory:

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Date and place of issue:

Watford

**Irina Proutski**

Person Responsible for Regulatory Compliance, Neomedic Limited



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## Appendix I

### List of devices, components and accessories

<b>ID</b>	<b>Trade Name</b>	<b>Class/Rule</b>
16142705	Latex Examination Gloves, Powdered, Extra Small	Class I/Rule 1
16142712	Latex Examination Gloves, Powdered, Small	Class I/Rule 1
16140206	Latex Examination Gloves, Powdered, Medium	Class I/Rule 1
16140336	Latex Examination Gloves, Powdered, Large	Class I/Rule 1
16140343	Latex Examination Gloves, Powdered, Extra Large	Class I/Rule 1
16140213	Latex Examination Gloves, Powder Free, Extra Small	Class I/Rule 1
16141074	Latex Examination Gloves, Powder Free, Small	Class I/Rule 1
16141081	Latex Examination Gloves, Powder Free, Medium	Class I/Rule 1
16141098	Latex Examination Gloves, Powder Free, Large	Class I/Rule 1
16141104	Latex Examination Gloves, Powder Free, Extra Large	Class I/Rule 1
16141401	Nitrile Examination Gloves, Powder Free, Extra Small	Class I/Rule 1
16141418	Nitrile Examination Gloves, Powder Free, Small	Class I/Rule 1
16141425	Nitrile Examination Gloves, Powder Free, Medium	Class I/Rule 1
16141432	Nitrile Examination Gloves, Powder Free, Large	Class I/Rule 1
16141449	Nitrile Examination Gloves, Powder Free, Extra Large	Class I/Rule 1



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