

EU Declaration of Conformity

Nytraguard Gloves

This declaration of conformity is issued under the sole responsibility of the manufacturer:
Robinson Healthcare Ltd., Lawn Road, Carlton-in-Lindrick, Worksop, Nottinghamshire, S81 9LB.

REF	Description
9525	Nytraguard® SkyBlue Nitrile Gloves – Extra Small
9526	Nytraguard® SkyBlue Nitrile Gloves – Small
9527	Nytraguard® SkyBlue Nitrile Gloves – Medium
9528	Nytraguard® SkyBlue Nitrile Gloves – Large
9529	Nytraguard® SkyBlue Nitrile Gloves – Extra Large
9531	Nytraguard® Tough Nitrile Gloves – Small
9532	Nytraguard® Tough Nitrile Gloves – Medium
9533	Nytraguard® Tough Nitrile Gloves – Large
9534	Nytraguard® Tough Nitrile Gloves – Extra Large
9531	Nytraguard® Tough Nitrile Gloves – Small
9535	Nytraguard® Bluple® Nitrile Gloves – Extra Small – 100 x 10
9536	Nytraguard® Bluple® Nitrile Gloves – Small – 100 x 10
9537	Nytraguard® Bluple® Nitrile Gloves – Medium – 100 x 10
9538	Nytraguard® Bluple® Nitrile Gloves – Large – 100 x 10
9539	Nytraguard® Bluple® Nitrile Gloves – Extra Large – 100 x 10
9545	Nytraguard® Bluple® Nitrile Gloves – Extra Small – 200 x 10
9546	Nytraguard® Bluple® Nitrile Gloves – Small – 200 x 10
9547	Nytraguard® Bluple® Nitrile Gloves – Medium – 200 x 10
9548	Nytraguard® Bluple® Nitrile Gloves – Large – 200 x 10
9549	Nytraguard® Bluple® Nitrile Gloves – Extra Large – 200 x 10

It is hereby certified that the products listed are in conformity with the requirements of Regulation (EU) 2016/425 on Personal Protective Equipment and Council Directive 93/42/EEC on Medical Devices, both as amended.

Classification

Class I, as defined by the application of classification rules 1 and 5 of Directive 93/42/EEC
Category I, as defined by Annex I of Regulation (EU) 2016/425

Conformity Assessment Route

The products are subject to Internal Production Control (Module A) as per Annex IV of Regulation (EU) 2016/425 for Category I PPE.

By the rules of Annex IX they have been placed in Class I for Medical Devices, as defined by classification rules 1 and 5 of the directive. The conformity route is that described in Annex VII of Directive 93/42/EEC.

Standards Applied

BS EN ISO 374-1:2016

BS EN ISO 374-2:2014

BS EN ISO 374-4:2013

BS EN ISO 374-5:2016

BS EN 16523-1:2015

BS EN 420:2003 + A1:2009

BS EN 455-1:2000

BS EN 455-2:2015

BS EN 455-3:2015

BS EN 455-3:2015

BS EN ISO 21171:2006

BS EN ISO 9001:2015

BS EN ISO 13485:2016

BS EN 1186-1:2002

ASTM D6978-05

ASTM F1342

ASTM F1671

Signed for and on behalf of Robinson Healthcare Ltd on 16 June 2020

A handwritten signature in black ink, appearing to read 'Nigel Brassington', with a horizontal line drawn through the bottom of the signature.

Nigel Brassington (Regulatory Affairs Manager)

Robinson Healthcare Ltd., Lawn Road, Carlton-In-Lindrick, Worksop, S81 9LB