

Document Reference: OT-DOC-004
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EU Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.


MANUFACTURER

Name of Company	Address
Polyco Healthline Ltd	South Fen Road, Bourne, Lincolnshire, PE10 0DN, UK.

EU IMPORTER

Name of Company	Address
Polyco Healthline Europe	13-18 City Quay, Dublin 2, Dublin, D02 ED70, Ireland

PRODUCT IDENTIFICATION

Product Name	Code / Catalogue Number
Otect N615 Sterile Nitrile Cleanroom Gloves	N615
Intended Purpose	Photograph
Cat III PPE for use in cleanrooms and offering a degree of chemical protection against the chemicals specified in the IFU.	

RISK CATEGORY OF PERSONAL PROTECTIVE EQUIPMENT AND PERFORMANCE LEVELS

Product Risk Category		
Personal Protective Equipment (PPE) Category III		
Standard	Performance Levels	
EN ISO 374-1:2016	Type B - KPT	
EN ISO 374-5:2016	Protection against bacteria and fungi	Protection against viruses
	Pass	Pass

Polyco Healthline Ltd declares that the above-mentioned product meets the provisions of the following EU legislation:

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- is classed as Category III PPE in conformity with the provisions of Regulation (EU) 2016/425 on personal protective equipment and with National Standards transposing harmonised standards EN ISO 374-1:2016, EN ISO 374-5:2016 and EN 420:2003+A1:2009.
- is identical to the personal protective equipment which is the subject of EU Type-Examination Certificate number 2777/11793-03/E04-01, issued by SATRA Technology Europe Limited, Bracetown Business Park, Clonee, Dublin, D15 YN2P, Republic of Ireland (Notified Body number 2777), according to Annex V (Module B) of Regulation (EU) 2016/425.
- is subject to the quality assurance conformity of the production process Module D set out in Annex VIII of Regulation (EU) 2016/425, under the surveillance of the notified body SGS FIMKO OY, Särkiniementie 3, 00211 Helsinki, Finland (Notified Body Number 0598).

COMPANY REPRESENTATIVE: David Langridge

TITLE: Head of Technical

SIGNATURE: 

PLACE: Bourne, UK

DATE: 21st January 2026