

Document Reference: OT-EUDOC-001  
 Document Issue Number: 03  
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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 N310 Nitrile Cleanroom Gloves	N310
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 + A1:2018	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 + A1:2018, EN ISO 374-5:2016 and EN ISO 21420:2020.
- is identical to the personal protective equipment which is the subject of EU Type-Examination Certificate number 2777/26004-03/E00-00, 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 conformity assessment procedure Module C2 set out in Annex VII of Regulation (EU) 2016/425, under the surveillance of the notified body SATRA Technology Europe Limited, Bracetown Business Park, Clonee, Dublin, D15 YN2P, Republic of Ireland (Notified Body number 2777).

**COMPANY REPRESENTATIVE:** David Langridge

**TITLE:** Head of Technical

**SIGNATURE:** 

**PLACE:** Bourne, UK

**DATE:** 10th February 2026