

EU Type Examination Certificate

This is to certify that:

Regal Polythene Limited
T/A Regal Disposables
Unit 2, Shell Green
Widnes
Cheshire
WA8 0GW
United Kingdom

Holds Certificate Number:

CE 716735

In respect of:

PVC Gloves for Personal Protection
See continuation sheets for details.

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified
Body for the above Regulation
(Notified Body Number 2797):

Previous Notified Body: BSI 0086

First Issued: 2019-11-20

Latest Issue: 2019-11-20



Drs. Dave Hagenaaars, Managing Director

Effective Date: 2019-11-20

Expiry Date: 2024-11-20

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...making excellence a habit.™

EU Type Examination Certificate

No. CE 716735

Product Specification

Models:

Powdered Synthetic Vinyl Gloves
**REGAL SAFETOUCH VINYL GLOVES POWDERED (CLEAR),
REGAL SAFETOUCH VINYL GLOVES POWDERED (BLUE)**

Powder Free Synthetic Vinyl Gloves
**REGAL SAFETOUCH VINYL GLOVES POWDER FREE (CLEAR),
REGAL SAFETOUCH VINYL GLOVES POWDER FREE (CLEAR) INDUSTRIAL,
REGAL SAFETOUCH VINYL GLOVES POWDER FREE (BLUE) and
REGAL SAFETOUCH SYNTHETIC VINYL GLOVES POWDER FREE**

Classification:

Protective gloves for use against micro-organisms and general applications.

PPE Category:

Category III - Complex.

Description:

PVC vinyl gloves, powdered or powder free, seamless with low chemical protection.
Ambidextrous glove with beaded cuff. Gloves are for single use only.

Size range:

XS, S, M, L and XL or 6, 7, 8, 9 and 10

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Performance

EN 420:2003+A1:2009 - General requirements:

Characteristic	Performance
Length and fit	Pass
pH value	Pass
Dexterity	Level 5

EN 374-2:2014 – Protection against penetration by micro-organisms. Determination of resistance to penetration.

Characteristic	Performance
Water Leak	Pass
Air Leak	Pass

EN 374-4:2013 – Resistance to degradation

Chemical	
40% Sodium Hydroxide (K)	-9.3%

EN ISO 374-1:2016 Resistance to chemical permeation to test method EN 16523-1:2015 Determination of resistance of permeation by chemicals.

Chemical	Permeation Level
40% Sodium Hydroxide (K)	6

Terminology and performance requirements for micro-organism Risks EN ISO 374-5:2016 (Test Method ISO 16604:2004)

Characteristic	Level
Protection against bacteria and fungi	Pass
Protection against viruses	Pass

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Certificate Administration Details

Products initially approved under BS certificate number CE 698521.

Certificate Amendment Record

Issue date	Comments	BSI Project Ref.
November 2019	First issue.	2797:19:3065616

Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall process utilised in the manufacture of the products, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes

The requirements for internal production control plus supervised product checks at random intervals, are referenced in BSI issued Module C2 Certificate Number CE 630603.

The validity of the Certificate is also dependent on the maintenance of a documented quality system.

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