

EC Type Examination Certificate

This is to certify that:

Import-Velez S.R.L
Av. Alvarez Thomas 1553
Buenos Aires
C1427CDC
Argentina

Holds Certificate Number:

CE 696101

In respect of:

Powdered Surgical Gloves
To EN 388:2003, EN 374-1:2003, EN 374-2:2003, EN 374-3:2003 and
EN 420:2003+A1:2009

On the basis of our examination, under the requirements of Council Directive 89/686/EEC "Personal Protective Equipment" Article 10, EC Type-Examination

For and on behalf of BSI, a Notified
Body for the above Directive
(Notified Body Number 0086):


Chris Lewis - Certification Director, Product Certification

First Issued: 2018-07-12

Latest Issue: 2018-07-12

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EC Type Examination Certificate

No. CE 696101

Product Specification

Model: VELEZ Guantes Esteriles De Cirugia Sensitivos Latex Bajo Polvo

Classification: Protective glove for use against chemical and micro-organism hazards.

Description: A powdered natural rubber latex glove with beaded cuff with smooth inner surface for ease of donning and doffing. The glove is available in a white colour and is hand specific.

Models in range: VELEZ Guantes Esteriles De Cirugia Sensitivos Latex Bajo Polvo

PPE Category: Category III – complex

Applicable standards: General requirements for gloves to EN 420:2003+A1:2009
Mechanical Hazards to EN 388:2003
Protective gloves against chemicals & micro-organisms to EN 374-1:2003
Resistance to penetration to EN 374-2:2003
Additional chemical tested in EN 374-3:2003

Performance: **General requirements for gloves to EN 420:2003+A1:2009**

Dexterity: Level 5

Mechanical Hazards to EN 388:2003

Abrasion resistance – level 0 Blade cut resistance – level 0

Tear resistance – level 0 Puncture resistance – level 0

Resistance to penetration to EN 374-2:2003

Pass

Resistance to permeation to chemical protection EN 374-3:2003

Diethylamine (G) – level 2 40% Sodium hydroxide (K) – level 3

96% Sulphuric acid (L) – level 2

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Product Specification (continued)

Performance:

Additional chemicals tested in the EN 374-3:2003 method

100mg/25ml Carmustine – level 2	1.5mg/ml Fluorouracil – level 4
50mg/100ml Cisplatin – level 4	10mg/ml Carboplatin - level 4
250mg/25ml Mitomycin – level 2	500 mg/25ml Cyclophosphamide – level 3
5% Glutaraldehyde – level 3	16g/l Methyl Methacrylate (MMA) – level 1

Certificate Administration Details

Product initially approved on BSI issued certificate CE 579727

Certificate Amendment Record

Issue date

Comments

July 2018

First issue.

BSI Internal report No.

0086:18:8993197

Note: The Certificate holder is responsible for keeping the Notified Body advised of changes to any aspect of the overall process used in the manufacture of the product.

Monitoring of manufactured PPE

The EC Quality of Production by Monitoring requirements, Article 11B, for the product are referenced in BSI issued Certificate Number CE 51699.

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