

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 696105

In respect of:

Powder Free Nitrile 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 696105

Product Specification

Model: VELEZ Guantes Esteriles De Cirugia Sensitivos sin Polvo Libre de Latex Nitrilo

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

Description: A powder free nitrile glove with beaded cuff with smooth inner surface for ease of donning and doffing. The glove is available in a natural colour (White).

Models in range: VELEZ Guantes Esteriles De Cirugia Sensitivos sin Polvo Libre de Latex Nitrilo

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

5% Glutaraldehyde – level 4

16g/l Methyl methacrylate – level 3

70% Isopropyl alcohol – level 2

500mg/25ml Cyclophosphamide – level 3

1mg/ml Adriamicin – level 3

50mg/100ml Cis Platin (II) Diammine – level 3

1.5mg/ml Fluorouracil – level 3

20mg/ml Etoposide – level 3

6mg/50ml Paclitaxel® - level 4

10mg/ml Thiotepa – level 3

10mg/ml Dacarbazina – level 3

50mg/ml Ifosfamide – level 3

2mg/ml Mitoxantrone – level 4

1mg/ml Vincristine sulphate salt – level 4

100mg/25ml Carmustine – level 3

150mg/ml Daunorubicin chloridrate – level 3

10mg/ml Carboplatin Diammine – level 3

250mg/25ml Mitomycin – level 3

1mg/ml Methotrexate – level 3

1mg/ml Vinblastine sulphate salt – level 3

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Certificate Administration Details

Product initially approved on BSI issued certificate CE 634780

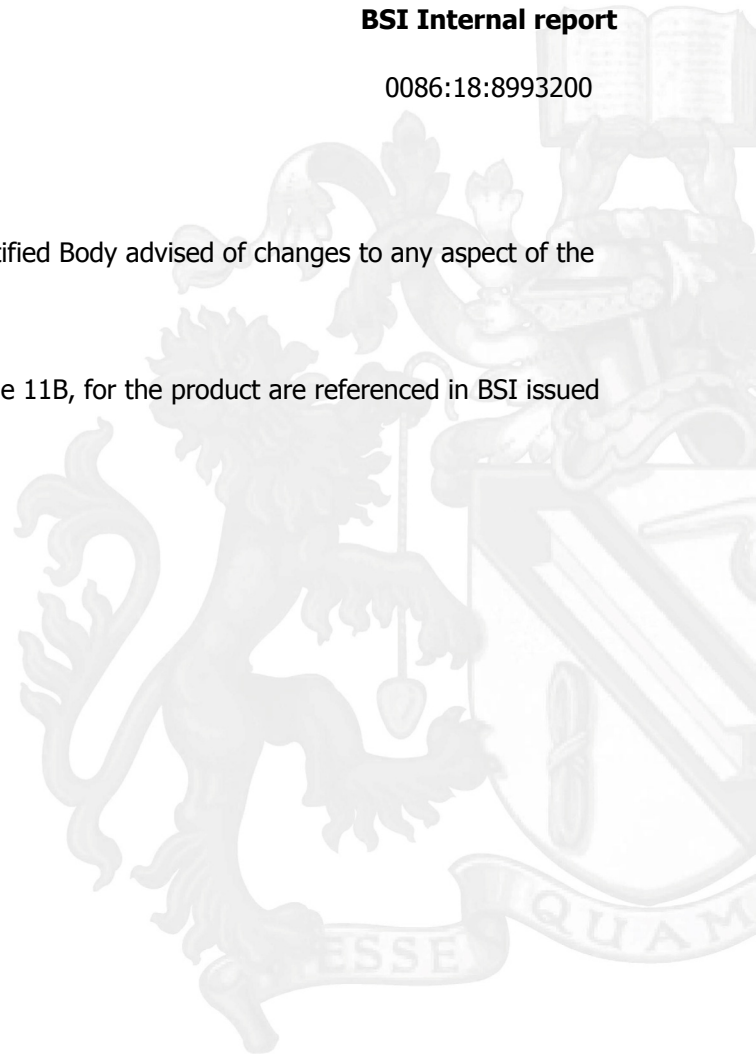
Certificate Amendment Record

Issue date	Comments	BSI Internal report
July 2018	First issue.	0086:18:8993200

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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