

EU Type Examination Certificate

This is to certify that:

Berner International GmbH
Werner-von-Siemens-Str. 19
25337 Elmshorn
Germany

Holds Certificate Number:

CE 710567

In respect of:

Powder Free Polychloroprene Surgical/Chemo Gloves

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 0086):


Chris Lewis - Certification Director, Product Certification

First Issued: 2019-05-15

Latest Issue: 2019-05-15

Effective Date: 2019-05-15

Expiry Date: 2024-05-15

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EU Type Examination Certificate

No. CE 710567

Product Specification

Models: **Berner Manu Prene XP (sterile)**
Berner Manu Prene XP (non-sterile)

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

Description: A powder free neoprene rubber glove with beaded cuff with smooth inner surface for ease of donning doffing. The glove is available in a light brown colour.

Models in range: Chloroprene Powder Free Surgical/Chemo Gloves

Category: Category III – complex

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

Standards: Protective gloves against chemicals & micro-organisms to EN ISO 374-1:2016

Resistance to penetration to EN 374-2:2014

Determination of resistance to permeation by chemicals tested to EN 16523-1:2015

Resistance to penetration by blood borne tested to EN ISO 374-5:2016

Resistance to degradation by chemicals to EN 374-4:2013

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Product Specification (Continued)

Models: **Berner Manu Prene XP (sterile)**
Berner Prene XP (non-sterile)

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

Dexterity: Level 5

Resistance to penetration to EN 374-2:2014

Pass

Resistance to chemical permeation to EN ISO 374-1:2016
Test method EN 16523-1:2015

40% Hydrofluoric acid (S) – level 5
40% Sodium hydroxide (K) – level 6
65% Nitric acid (M) – level 6
37% Formaldehyde (T) – level 6
30% Hydrogen peroxide (P) – level 6
96% Sulphuric acid (L) – level 2

Resistance to penetration by blood borne tested to EN ISO 374-5:2016

Pass

Resistance to degradation by chemicals to EN 374-4:2013

30% Hydrogen peroxide (P) -10.2%
40% Sodium hydroxide (K) -18.0%
37% Formaldehyde (T) -4.1%
96% Sulphuric acid (L) 8.2%
65% Nitric acid (M) -4.6%

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Certificate Administration Details

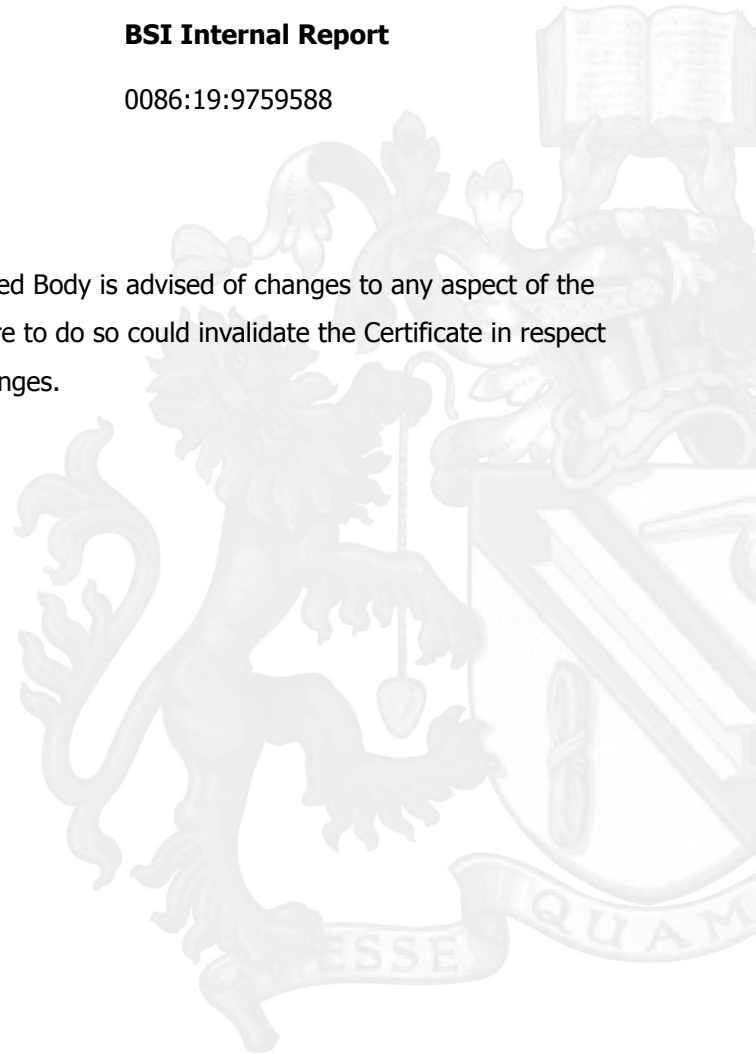
Products initially approved under BSI Certificate number CE 688312.

Certificate Amended Record

Issue Date	Comments	BSI Internal Report
May 2019	First Issue	0086:19:9759588

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 product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.



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