

# EU Type Examination Certificate

This is to certify that:

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

Holds Certificate Number:

CE 710563

In respect of:

## **NR Latex Examination Glove (Chemo) Berner Manu L**

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 710563

## Product Specification

<b>Models:</b>	<b>Berner Manu L (sterile)</b> <b>Berner Manu L (non-sterile)</b>
<b>Classification:</b>	Protective glove for use against chemical and micro-organism hazards. Designed for single use.
<b>Description:</b>	A powder free natural rubber latex glove. The glove is available in a natural and blue colour.
<b>Models in range:</b>	Natural rubber powder free chemotherapy protection glove
<b>PPE Category:</b>	Category III – complex
<b>Applicable standards:</b>	General requirements for gloves to EN 420:2003+A1:2009.  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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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A member of BSI Group of Companies.

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No. CE 710563

## Product Specification

**Models:** **Berner Manu L (sterile)**  
**Berner Manu L (non-sterile)**

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

Dexterity: Level 5

Extractable protein content (EN 455-3): < 50 µg/g

**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% Sodium hydroxide (K) – level 6

30% Hydrogen peroxide (P) – level 6

37% Formaldehyde (T) – level 6

**Resistance to penetration by blood borne tested to EN ISO 374-5:2015**

Pass

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

30% Hydrogen peroxide (P) 12.5%

37% Formaldehyde (T) -3.1%

40% Sodium hydroxide (K) -6.5%

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## Certificate Administration Details

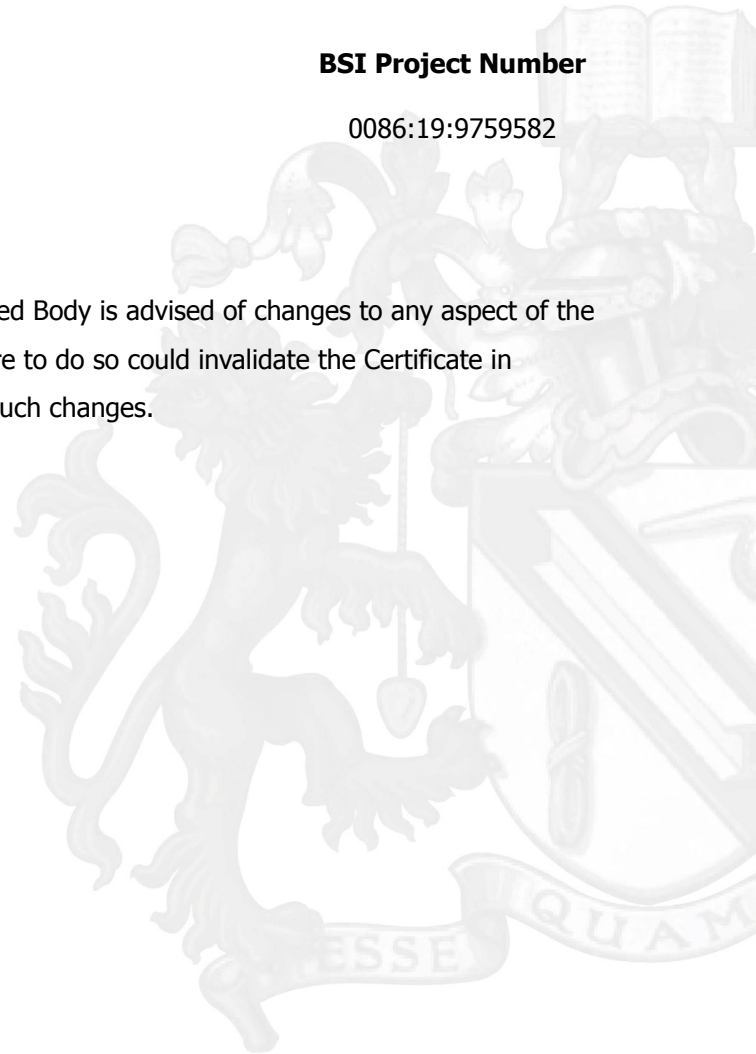
Product initially approved under BSI certificate number CE 688307.

## Certificate Amendment Record

Issue date	Comments	BSI Project Number
May 2019	First issue.	0086:19:9759582

## 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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