

EU Type Examination Certificate

This is to certify that:

Mölnlycke Health Care AB
Gamlestadsvägen 3C
Box 13080
Göteborg
SE-402 52
Sweden

Holds Certificate Number:

CE 687999

In respect of:

Biogel® gloves for Personal Protection.
Various models, see continuation sheets for details.

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

For and on behalf of BSI:


Chris Lewis - Certification Director, Product Certification

First Issued: 2018-08-21
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EU Type Examination Certificate

No. CE 687999

Product Specification

PPE Category: Category III - Complex.

Applicable Standards: The following Harmonized European Standards:

EN 420:2003+A1:2009 - Protective gloves. General requirements.

EN 374-1:2016 - Protective gloves against chemicals and micro-organisms - Terminology and performance requirements.

EN 374-2:2014 - Protective gloves against dangerous chemicals and micro-organisms - Determination of resistance to penetration.

EN 374-4:2013 – Protective gloves against chemicals and micro-organisms. Determination of resistance to degradation by chemicals.

EN 374-5:2016 – Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organism risks.

EN 16523-1:2015 - Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to permeation by chemicals.

EN 16604:2004 – Clothing for protection against contact with blood and body fluids. Determination of resistance of protective clothing materials to penetration by blood-borne pathogens. Test method using Phi-X174 Bacteriophage.

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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
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EU Type Examination Certificate

No. CE 687999

Model: Biogel® NeoTech S44509 (formerly Skinsense®)

Product Code: S44509XX
Size range 5.5 to 9

Classification: Protective gloves for use against micro-organisms and general applications. Designed for single use by individuals including those who are sensitive to natural rubber latex to provide cover to the hands and wrists.

Description : A sterile, powder-free, synthetic polychloroprene surgical overglove with polymeric inner surface treatment to assist donning. The glove provides a barrier to protect against cross-infection.

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

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

EN 374-2:2014 – Resistance to penetration

Performance Level 3

EN 374-4:2013 – Resistance to degradation

Tested for all chemicals listed below.

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

Chemical	Permeation Level
40% Sodium Hydroxide (K)	6

EN 16604:2004 Resistance to penetration by blood-borne pathogens

Pass

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EU Type Examination Certificate

No. CE 687999

Model: Biogel® Tech
Product Code: S44822XX
Size range 5.5 to 9

Classification: Protective gloves for use against micro-organisms and general applications. Designed for single use and to provide cover to the hands and wrists, provides low chemical protection.

Description : A sterile, powder-free, natural rubber latex surgical glove with polymeric inner surface treatment. The glove is anatomically shaped, has curved fingers and a smooth finish.

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

Characteristic	Performance
pH value	Pass
Dexterity	Level 5
Length and Fit	Pass
Protein Content	<50µg/g

EN 374-2:2014 – Resistance to penetration

Performance Level 3

EN 374-4:2013 – Resistance to degradation

Tested for all chemicals listed below.

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

Chemical	Permeation Level
40% Sodium Hydroxide (K)	6

EN 16604:2004 Resistance to penetration by blood-borne pathogens

Pass

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EU Type Examination Certificate

No. CE 687999

Model: Biogel® Tech

Product Code: S44961XX
Size range 5.5 to 9

Classification: Protective gloves for use against micro-organisms and general applications. Designed for single use and to provide cover to the hands and wrists.

Description : A sterile, powder-free, natural rubber latex surgical glove with polymeric inner surface treatment. The glove is anatomically shaped, has straight fingers and a micro rough finish.

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

Characteristic	Performance
pH value	Pass
Dexterity	Level 5
Length and Fit	Pass
Protein Content	<50µg/g

EN 374-2:2014 – Resistance to penetration

Performance Level 3

EN 374-4:2013 – Resistance to degradation

Tested for all chemicals listed below.

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

Chemical	Permeation Level
40% Sodium Hydroxide (K)	6

EN 16604:2004 Resistance to penetration by blood-borne pathogens

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No. CE 687999

Model: Biogel® PI Tech S44409 (formerly PI Ultratouch)

Product Code: S44409XX
Size range 5.5 to 9

Classification: Protective gloves for use against micro-organisms and general applications. Designed for single use by individuals including those who are sensitive to natural rubber latex to provide cover to the hands and wrists.

Description : A sterile, powder-free, transparent synthetic polyisoprene surgical overglove with polymeric inner surface treatment to assist donning. The glove provides a barrier to protect against cross-infection.

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

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

EN 374-2:2014 – Resistance to penetration

Performance Level 3

EN 374-4:2013 – Resistance to degradation

Tested for all chemicals listed below.

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

Chemical	Permeation Level
40% Sodium Hydroxide (K)	6

EN 16604:2004 Resistance to penetration by blood-borne pathogens

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EU Type Examination Certificate

No. CE 687999

Model: Biogel® PI Tech Indicator Underglove

Product Code: S44416XX
Size range 5.5 to 9

Classification: Protective gloves for use against micro-organisms and general applications. Designed for single use by individuals including those who are sensitive to natural rubber latex to provide cover to the hands and wrists.

Description : A sterile, powder-free, blue synthetic polyisoprene surgical underglove with polymeric inner surface treatment to assist donning. The glove provides a barrier to protect against cross-infection.

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

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

EN 374-2:2014 – Resistance to penetration

Performance Level 3

EN 374-4:2013 – Resistance to degradation

Tested for all chemicals listed below.

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

Chemical	Permeation Level
40% Sodium Hydroxide (K)	6

EN 16604:2004 Resistance to penetration by blood-borne pathogens

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Certificate Administration Details

Technical File Reference: PPE Technical Files - Biogel® NRL Critical Environment Gloves and Biogel® Synthetic Critical Environment Gloves.

Certificate Administration Record and BSI internal Technical File Review reference

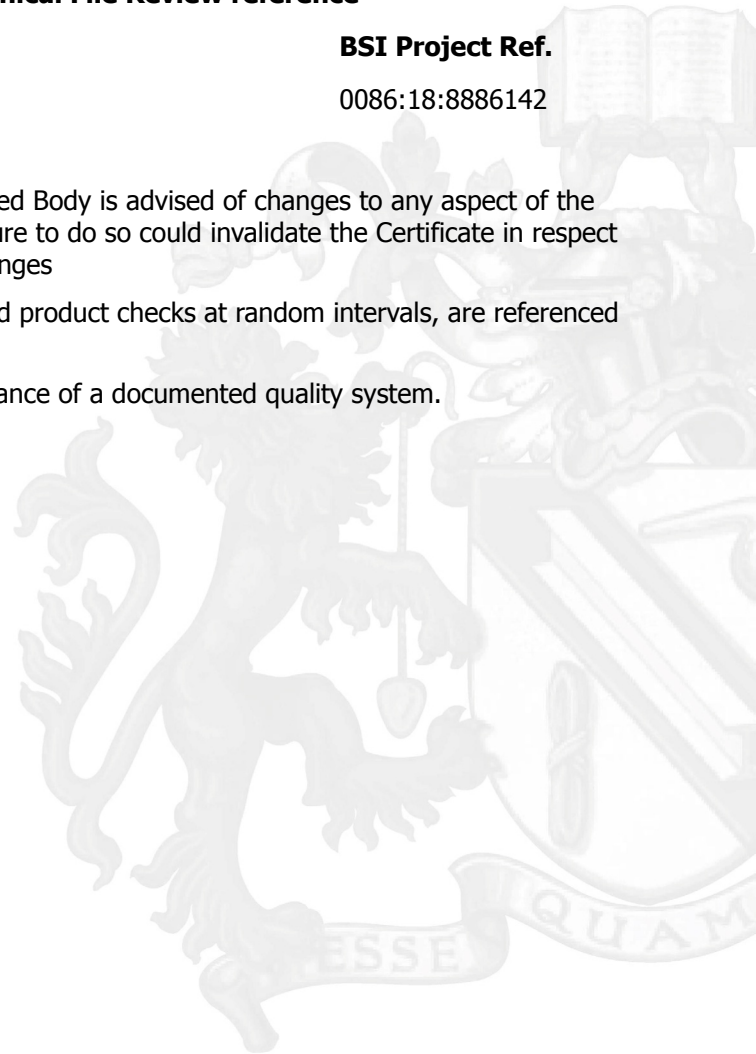
Issue date	Comments	BSI Project Ref.
August 2018	First Issue	0086:18:8886142

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 Certificate Number CE 578631.

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



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