

# 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 699813

In respect of:

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

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 2797):

Previous Notified Body: BSI 0086

First Issued: 2019-02-05

Latest Issue: 2019-09-12



Drs. Dave Hagenaaars, Managing Director

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Page: 1 of 25



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# EU Type Examination Certificate

No. CE 699813

## Product Specification

**Classification:** Protective gloves for use against microorganisms and general applications. Designed for single use and to provide cover to the hands and wrists.

**Applicable** The following Harmonized European Standards:

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

EN ISO 374-1:2016 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.

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

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

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

EN 16523-1:2015 Determination of material resistance to permeation by chemicals. Permeation by liquid chemical under conditions of continuous contact.

ISO 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.

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Effective Date: 2019-09-12

Expiry Date: 2024-02-05

Page: 2 of 25

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# EU Type Examination Certificate

No. CE 699813

## Product Specification

**Model:** Biogel® Skinsense®

**Product code:** S509XX

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

**Performance:** **Resistance to chemical permeation to EN ISO 374-1:2016**  
**Type C** Low chemical protection (Test method EN 16523-1:2015)

<b>Chemical</b>	<b>Level</b>
Sodium Hydroxide 40% (K)	6

### Protection against micro-organism risks to EN ISO 374-5:2016

Bacteria and fungi (Test method EN 374-2:2014)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

### Resistance to degradation to EN 374-4:2013

Tested against Sodium Hydroxide 40%

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

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Size Range:</b>	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9

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Effective Date: 2019-09-12

Expiry Date: 2024-02-05

Page: 3 of 25

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# EU Type Examination Certificate

No. CE 699813

**Model:** Biogel® Skinsense® Indicator® Underglove

**Product code:** S406XX

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

**Performance:** **Resistance to chemical permeation to EN ISO 374-1:2016**  
**Type C** Low chemical protection (Test method EN 16523-1:2015)

<b>Chemical</b>	<b>Level</b>
Sodium Hydroxide 40% (K)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN 374-2:2014)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

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

Tested against Sodium Hydroxide 40%

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

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Size Range:</b>	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9

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Effective Date: 2019-09-12

Expiry Date: 2024-02-05

Page: 4 of 25

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# EU Type Examination Certificate

No. CE 699813

**Model:** Biogel® Skinsense® Indicator® System

**Product code:** S288XX

**Description:** The glove system consists of two products: underglove S406XX and overglove S509XX, both are made as sterile, powder-free synthetic polychloroprene gloves with polymeric inner surface treatment. The glove system S288XX is primarily used to provide a double barrier against cross infections and for the purpose of puncture indication.

**Performance:** **Resistance to chemical permeation to EN ISO 374-1:2016**

**Type C** Low chemical protection (Test method EN 16523-1:2015)

<b>Chemical</b>	<b>Level</b>
Sodium Hydroxide 40% (K)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN 374-2:2014)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

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

Tested against Sodium Hydroxide 40%

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

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Size Range:</b>	5.5, 6, 6.5, 7, 7.5, 8, 8.5

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Expiry Date: 2024-02-05

Page: 5 of 25

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# EU Type Examination Certificate

No. CE 699813

**Model:** Biogel® Surgeons

**Product code:** S822XX

**Description:** A sterile, powder-free, transparent, natural rubber latex surgical overglove with polymeric inner surface treatment to assist donning.

**Performance:** **Resistance to chemical permeation to EN ISO 374-1:2016**  
**Type C** Low chemical protection (Test method EN 16523-1:2015)

Chemical	Level
Sodium Hydroxide 40% (K)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN 374-2:2014)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

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

Tested against Sodium Hydroxide 40%.

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

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Extractable protein:</b>	<50µg/g
<b>Size Range:</b>	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9

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Expiry Date: 2024-02-05

Page: 6 of 25

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# EU Type Examination Certificate

No. CE 699813

**Model:** Biogel® Surgeons

**Product code:** S961XX

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

**Performance:** **Resistance to chemical permeation to EN ISO 374-1:2016**  
**Type C** Low chemical protection (Test method EN 16523-1:2015)

<b>Chemical</b>	<b>Level</b>
Sodium Hydroxide 40% (K)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN 374-2:2014)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

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

Tested against Sodium Hydroxide 40%.

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

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Extractable protein:</b>	<50µg/g
<b>Size Range:</b>	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9

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Effective Date: 2019-09-12

Expiry Date: 2024-02-05

Page: 7 of 25

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# EU Type Examination Certificate

No. CE 699813

**Model:** Biogel® PI UltraTouch®

**Product code:** S409XX

**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.

**Performance:** **Resistance to chemical permeation to EN ISO 374-1:2016**  
**Type C** Low chemical protection (Test method EN 16523-1:2015)

<b>Chemical</b>	<b>Level</b>
Sodium Hydroxide 40% (K)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN 374-2:2014)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

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

Tested against Sodium Hydroxide 40%.

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

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Size Range:</b>	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9

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Effective Date: 2019-09-12

Expiry Date: 2024-02-05

Page: 8 of 25

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# EU Type Examination Certificate

No. CE 699813

**Model:** **Biogel PI Indicator® Underglove**

**Product code:** **S416XX**

**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.

**Performance:** **Resistance to chemical permeation to EN ISO 374-1:2016**  
**Type C** Low chemical protection (Test method EN 16523-1:2015)

<b>Chemical</b>	<b>Level</b>
Sodium Hydroxide 40% (K)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN 374-2:2014)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

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

Tested against Sodium Hydroxide 40%.

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

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Size Range:</b>	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9

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Effective Date: 2019-09-12

Expiry Date: 2024-02-05

Page: 9 of 25

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# EU Type Examination Certificate

No. CE 699813

**Model:** **Biogel PI Indicator® System**

**Product code:** **S414XX**

**Description:** The glove system consists of two products: underglove S416XX and overglove S409XX, both are made as sterile, powder-free synthetic polyisoprene gloves with polymeric inner surface treatment. The glove system S414XX is primarily used to provide a double barrier against cross infections and for the purpose of puncture indication.

**Performance:** **Resistance to chemical permeation to EN ISO 374-1:2016**  
**Type C** Low chemical protection (Test method EN 16523-1:2015)

<b>Chemical</b>	<b>Level</b>
Sodium Hydroxide 40% (K)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN 374-2:2014)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

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

Tested against Sodium Hydroxide 40%.

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

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Size Range:</b>	5.5, 6, 6.5, 7, 7.5, 8, 8.5

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Effective Date: 2019-09-12

Expiry Date: 2024-02-05

Page: 10 of 25

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# EU Type Examination Certificate

No. CE 699813

**Model:** Biogel Eclipse®

**Product code:** S751XX

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

**Performance:** **Resistance to chemical permeation to EN ISO 374-1:2016**  
**Type C** Low chemical protection (Test method EN 16523-1:2015)

Chemical	Level
Sodium Hydroxide 40% (K)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN 374-2:2014)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

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

Tested against Sodium Hydroxide 40%.

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

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Extractable protein:</b>	<50 µg/g
<b>Size Range:</b>	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9

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Page: 11 of 25

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# EU Type Examination Certificate

No. CE 699813

**Model:** **Biogel Eclipse® Indicator® Underglove**

**Product code:** **S732XX**

**Description:** A sterile, powder-free, green, natural rubber latex surgical underglove with polymeric inner surface treatment to assist donning. The glove provides a barrier to protect against cross-infection.

**Performance:** **Resistance to chemical permeation to EN ISO 374-1:2016**  
**Type C** Low chemical protection (Test method EN 16523-1:2015)

<b>Chemical</b>	<b>Level</b>
Sodium Hydroxide 40% (K)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN 374-2:2014)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

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

Tested against Sodium Hydroxide 40%.

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

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Extractable protein:</b>	<50 µg/g
<b>Size Range:</b>	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9

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Page: 12 of 25

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# EU Type Examination Certificate

No. CE 699813

**Model:** **Biogel Eclipse® Indicator® System**

**Product code:** **S607XX**

**Description:** The glove system consists of two products: underglove S732XX and overglove S751XX, both are made as sterile, powder-free, natural rubber latex gloves with polymeric inner surface treatment. The glove system S607XX is primarily used to provide a double barrier against cross infections and for the purpose of puncture indication.

**Performance:** **Resistance to chemical permeation to EN ISO 374-1:2016**  
**Type C** Low chemical protection (Test method EN 16523-1:2015)

<b>Chemical</b>	<b>Level</b>
Sodium Hydroxide 40% (K)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN 374-2:2014)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

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

Tested against Sodium Hydroxide 40%.

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

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Extractable protein:</b>	<50 µg/g
<b>Size Range:</b>	5.5, 6, 6.5, 7, 7.5, 8, 8.5

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Effective Date: 2019-09-12

Expiry Date: 2024-02-05

Page: 13 of 25

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# EU Type Examination Certificate

No. CE 699813

**Model:** Biogel® Super-Sensitive

**Product code:** S825XX

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

**Performance:** **Resistance to chemical permeation to EN ISO 374-1:2016**  
**Type C** Low chemical protection (Test method EN 16523-1:2015)

Chemical	Level
Sodium Hydroxide 40% (K)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN 374-2:2014)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

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

Tested against Sodium Hydroxide 40%.

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

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Extractable protein:</b>	<50 µg/g
<b>Size Range:</b>	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9

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Page: 14 of 25

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# EU Type Examination Certificate

No. CE 699813

**Model:** **Biogel Indicator® System**

**Product code:** **S842XX**

**Description:** The glove system consists of two products: underglove S312XX and overglove S825XX, both are made as sterile, powder-free, natural rubber latex gloves with polymeric inner surface treatment. The glove system S842XX is primarily used to provide a double barrier against cross infections and for the purpose of puncture indication.

**Performance:** **Resistance to chemical permeation to EN ISO 374-1:2016**  
**Type C** Low chemical protection (Test method EN 16523-1:2015)

<b>Chemical</b>	<b>Level</b>
Sodium Hydroxide 40% (K)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN 374-2:2014)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

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

Tested against Sodium Hydroxide 40%.

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

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Extractable protein:</b>	<50 µg/g
<b>Size Range:</b>	5.5, 6, 6.5, 7, 7.5, 8, 8.5

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Page: 15 of 25

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# EU Type Examination Certificate

No. CE 699813

**Model:** Biogel® Skinsense® (non-sterile)

**Product code:** S33509XX

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

**Performance:** **Resistance to chemical permeation to EN ISO 374-1:2016**  
**Type C** Low chemical protection (Test method EN 16523-1:2015)

Chemical	Level
Sodium Hydroxide 40% (K)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN 374-2:2014)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

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

Tested against Sodium Hydroxide 40%.

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

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Size Range:</b>	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9

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Page: 16 of 25

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# EU Type Examination Certificate

No. CE 699813

**Model:** Biogel® Skinsense® Indicator® Underglove (non-sterile)

**Product code:** S33406XX

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

**Performance:** **Resistance to chemical permeation to EN ISO 374-1:2016**  
**Type C** Low chemical protection (Test method EN 16523-1:2015)

Chemical	Level
Sodium Hydroxide 40% (K)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN 374-2:2014)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

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

Tested against Sodium Hydroxide 40%.

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

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Size Range:</b>	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9

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Latest Issue: 2019-09-12

Effective Date: 2019-09-12

Expiry Date: 2024-02-05

Page: 17 of 25

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# EU Type Examination Certificate

No. CE 699813

**Model:** Biogel® PI Micro

**Product code:** S485XX

**Description:** A sterile, powder-free, transparent, polyisoprene surgical overglove. The glove provides a barrier to protect against cross-infection.

**Performance:** **Resistance to chemical permeation to EN ISO 374-1:2016**  
**Type C** Low chemical protection (Test method EN 16523-1:2015)

<b>Chemical</b>	<b>Level</b>
Sodium Hydroxide 40% (K)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN 374-2:2014)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

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

Tested against Sodium Hydroxide 40%.

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

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Size Range:</b>	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9

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Latest Issue: 2019-09-12

Effective Date: 2019-09-12

Expiry Date: 2024-02-05

Page: 18 of 25

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# EU Type Examination Certificate

No. CE 699813

**Model:** Biogel® PI Micro Indicator® Underglove

**Product code:** S489XX

**Description:** A sterile, powder-free, blue, polyisoprene surgical underglove. The glove provides a barrier to protect against cross-infection.

**Performance:** **Resistance to chemical permeation to EN ISO 374-1:2016**  
**Type C** Low chemical protection (Test method EN 16523-1:2015)

<b>Chemical</b>	<b>Level</b>
Sodium Hydroxide 40% (K)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN 374-2:2014)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

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

Tested against Sodium Hydroxide 40%.

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

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Size Range:</b>	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9

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Effective Date: 2019-09-12

Expiry Date: 2024-02-05

Page: 19 of 25

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# EU Type Examination Certificate

No. CE 699813

**Model:** Biogel® PI Micro Indicator® System

**Product code:** S483XX

**Description:** The glove system consists of two products: underglove S489XX and overglove S485XX, both are made as sterile, powder-free polyisoprene gloves. The glove system S483XX is primarily used to provide a double barrier against cross infections and for the purpose of puncture indication.

**Performance:** **Resistance to chemical permeation to EN ISO 374-1:2016**  
**Type C** Low chemical protection (Test method EN 16523-1:2015)

Chemical	Level
Sodium Hydroxide 40% (K)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN 374-2:2014)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

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

Tested against Sodium Hydroxide 40%.

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

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Size Range:</b>	5.5, 6, 6.5, 7, 7.5, 8, 8.5

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Effective Date: 2019-09-12

Expiry Date: 2024-02-05

Page: 20 of 25

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# EU Type Examination Certificate

No. CE 699813

**Model:** Biogel® PI UltraTouch® S

**Product code:** 455XX

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

**Performance:** **Resistance to chemical permeation to EN ISO 374-1:2016**  
**Type C** Low chemical protection (Test method EN 16523-1:2015)

<b>Chemical</b>	<b>Level</b>
Sodium Hydroxide 40% (K)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN 374-2:2014)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

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

Tested against Sodium Hydroxide 40%.

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

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Size Range:</b>	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9

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Effective Date: 2019-09-12

Expiry Date: 2024-02-05

Page: 21 of 25

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# EU Type Examination Certificate

No. CE 699813

**Model:** Biogel® PI UltraTouch® S Indicator® Underglove

**Product code:** 459XX

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

**Performance:** **Resistance to chemical permeation to EN ISO 374-1:2016**  
**Type C** Low chemical protection (Test method EN 16523-1:2015)

Chemical	Level
Sodium Hydroxide 40% (K)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN 374-2:2014)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

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

Tested against Sodium Hydroxide 40%.

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

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Size Range:</b>	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9

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Expiry Date: 2024-02-05

Page: 22 of 25

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# EU Type Examination Certificate

No. CE 699813

**Model:** Biogel® PI UltraTouch® S Indicator® System

**Product code:** 453XX

**Description:** The glove system consists of two products: underglove 459XX and overglove 455XX, both are made as sterile, powder-free polyisoprene gloves with polymeric inner surface treatment. The glove system 453XX is primarily used to provide a double barrier against cross infections and for the purpose of puncture indication.

**Performance:** **Resistance to chemical permeation to EN ISO 374-1:2016**  
**Type C** Low chemical protection (Test method EN 16523-1:2015)

<b>Chemical</b>	<b>Level</b>
Sodium Hydroxide 40% (K)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN 374-2:2014)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

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

Tested against Sodium Hydroxide 40%.

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

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Size Range:</b>	5.5, 6, 6.5, 7, 7.5, 8, 8.5

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Latest Issue: 2019-09-12

Effective Date: 2019-09-12  
Expiry Date: 2024-02-05

Page: 23 of 25

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# EU Type Examination Certificate

No. CE 699813

## Certificate Administration Details

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

Certificate Amendment Record:

Issue date	Comments	BSI Project Ref.
February 2019	First Issue	0086:19:9648030
June 2019	Addition of Biogel® PI UltraTouch® S range.	0086:19:9753144

## 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.

The validity of the Certificate for the products is also dependent on the maintenance of the EU Conformity to Type based on Internal Production Control plus supervised product checks at random intervals, Annex VII (Module C2) as referenced on BSI issued Certificate CE 578631.

First Issued: 2019-02-05

Latest Issue: 2019-09-12

Effective Date: 2019-09-12

Expiry Date: 2024-02-05

Page: 24 of 25

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# EU Type Examination Certificate

No. CE 699813

## Location

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

## Certified Activities

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



First Issued: 2019-02-05

Latest Issue: 2019-09-12

Effective Date: 2019-09-12

Expiry Date: 2024-02-05

Page: 25 of 25

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