

EU Type Examination Certificate

This is to certify that:

Mölnlycke Health Care AB
PO Box 130 80
Gamlestadsvagen
Göteborg
402 52
Sweden

Holds Certificate Number:

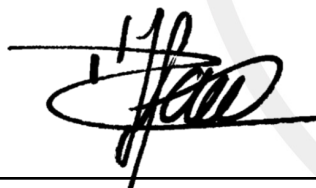
CE 699813

In respect of:

**Biogel® gloves for Personal Protection.
Various models.**

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):



Drs. Dave Hagenaaars, Managing Director

First Issued: 2019-02-05

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Expiry Date: 2024-02-05

Page: 1 of 23



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EU Type Examination Certificate

No. CE 699813

Product Specification

PPE Category: Category III - Complex.

Technical Specification: The following European Standards:

EN ISO 21420:2020 Protective gloves. General requirements and test methods.

EN ISO 374-1:2016+A1:2018 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.

EN ISO 374-2:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to penetration. (Test Method)

EN ISO 374-4:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to degradation by chemicals. (Test Method)

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+A1:2018 Determination of material resistance to permeation by chemicals. Permeation by potentially hazardous liquid chemicals under conditions of continuous contact. (Test Method)

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. Test method using Phi-X174 Bacteriophage. (Test Method)

First Issued: 2019-02-05

Latest Issue: 2021-11-02

Effective Date: 2021-11-02

Expiry Date: 2024-02-05

Page: 2 of 23

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EU Type Examination Certificate

No. CE 699813

Product Specification

Model: Biogel® Skinsense®

Product Code: S509XX

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 polychloroprene surgical overglove with polymeric inner surface treatment to assist donning. The glove is anatomically shaped, has curved fingers.

Performance: **Resistance to penetration to EN ISO 374-2:2019**

Performance Level 3

Resistance to degradation to EN ISO 374-4:2019

Tested for all chemicals listed below.

Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018

Type A Chemical protection (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6
30% Hydrogen Peroxide (P)	6
37% Formaldehyde (T)	6
96% Sulphuric Acid (L)	3
65% Nitric Acid (M)	6
99% Acetic Acid (N)	2

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

Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

General requirements for gloves to EN ISO 21420:2020

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

First Issued: 2019-02-05

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Effective Date: 2021-11-02

Expiry Date: 2024-02-05

Page: 3 of 23

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No. CE 699813

Model:	Biogel® Skinsense® Indicator® Underglove																		
Product Code:	S406XX																		
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 polychloroprene surgical underglove with polymeric inner surface treatment to assist donning. The glove is anatomically shaped, has curved fingers.																		
Performance:	Resistance to penetration to EN ISO 374-2:2019 Performance Level 3 Resistance to degradation to EN ISO 374-4:2019 Tested for all chemicals listed below. Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018 Type B Chemical protection (Test method EN 16523-1:2015+A1:2018) <table><thead><tr><th>Chemical</th><th>Level</th></tr></thead><tbody><tr><td>40% Sodium Hydroxide (K)</td><td>6</td></tr><tr><td>30% Hydrogen Peroxide (P)</td><td>5</td></tr><tr><td>37% Formaldehyde (T)</td><td>6</td></tr></tbody></table> Protection against micro-organism risks to EN ISO 374-5:2016 <table><tbody><tr><td>Bacteria and fungi (Test method EN ISO 374-2:2019)</td><td>Pass</td></tr><tr><td>Viruses (Test Method ISO 16604:2004)</td><td>Pass</td></tr></tbody></table> General requirements for gloves to EN ISO 21420:2020 <table><tbody><tr><td>Dexterity:</td><td>Level 5</td></tr><tr><td>pH:</td><td>Pass</td></tr><tr><td>Size Range:</td><td>5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9</td></tr></tbody></table>	Chemical	Level	40% Sodium Hydroxide (K)	6	30% Hydrogen Peroxide (P)	5	37% Formaldehyde (T)	6	Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass	Viruses (Test Method ISO 16604:2004)	Pass	Dexterity:	Level 5	pH:	Pass	Size Range:	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9
Chemical	Level																		
40% Sodium Hydroxide (K)	6																		
30% Hydrogen Peroxide (P)	5																		
37% Formaldehyde (T)	6																		
Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass																		
Viruses (Test Method ISO 16604:2004)	Pass																		
Dexterity:	Level 5																		
pH:	Pass																		
Size Range:	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9																		

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Page: 4 of 23

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EU Type Examination Certificate

No. CE 699813

Model: Biogel® Skinsense® Indicator® System

Product Code: S288XX

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: 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 penetration to EN ISO 374-2:2019**

Performance Level 3

Resistance to degradation to EN ISO 374-4:2019

Tested for all chemicals listed below.

Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018

Type B Chemical protection (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6
30% Hydrogen Peroxide (P)	5
37% Formaldehyde (T)	6

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

Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

General requirements for gloves to EN ISO 21420:2020

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

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Expiry Date: 2024-02-05

Page: 5 of 23

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No. CE 699813

Model:	Biogel® Skinsense® Indicator® Underglove (non-sterile)																		
Product Code:	S33406XX																		
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 non-sterile, powder-free, blue synthetic polychloroprene surgical underglove with polymeric inner surface treatment to assist donning. The glove is anatomically shaped, has curved fingers.																		
Performance:	Resistance to penetration to EN ISO 374-2:2019 Performance Level 3 Resistance to degradation to EN ISO 374-4:2019 Tested for all chemicals listed below. Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018 Type B Chemical protection (Test method EN 16523-1:2015+A1:2018) <table><thead><tr><th>Chemical</th><th>Level</th></tr></thead><tbody><tr><td>40% Sodium Hydroxide (K)</td><td>6</td></tr><tr><td>30% Hydrogen Peroxide (P)</td><td>5</td></tr><tr><td>37% Formaldehyde (T)</td><td>6</td></tr></tbody></table> Protection against micro-organism risks to EN ISO 374-5:2016 <table><tbody><tr><td>Bacteria and fungi (Test method EN ISO 374-2:2019)</td><td>Pass</td></tr><tr><td>Viruses (Test Method ISO 16604:2004)</td><td>Pass</td></tr></tbody></table> General requirements for gloves to EN ISO 21420:2020 <table><tbody><tr><td>Dexterity:</td><td>Level 5</td></tr><tr><td>pH:</td><td>Pass</td></tr><tr><td>Size Range:</td><td>5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9</td></tr></tbody></table>	Chemical	Level	40% Sodium Hydroxide (K)	6	30% Hydrogen Peroxide (P)	5	37% Formaldehyde (T)	6	Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass	Viruses (Test Method ISO 16604:2004)	Pass	Dexterity:	Level 5	pH:	Pass	Size Range:	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9
Chemical	Level																		
40% Sodium Hydroxide (K)	6																		
30% Hydrogen Peroxide (P)	5																		
37% Formaldehyde (T)	6																		
Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass																		
Viruses (Test Method ISO 16604:2004)	Pass																		
Dexterity:	Level 5																		
pH:	Pass																		
Size Range:	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9																		

First Issued: 2019-02-05

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Effective Date: 2021-11-02

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Page: 6 of 23

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No. CE 699813

Model:	Biogel® Surgeons														
Product Code:	S822XX														
Classification:	Protective gloves for use against micro-organisms and general applications. Designed for single use by individuals and to provide cover to the hands and wrists.														
Description:	A sterile, powder-free, transparent natural rubber latex surgical overglove with polymeric inner surface treatment to assist donning. The glove is anatomically shaped, has curved fingers.														
Performance:	Resistance to penetration to EN ISO 374-2:2019 Performance Level 3 Resistance to degradation to EN ISO 374-4:2019 Tested for all chemicals listed below. Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018 Type C Chemical protection (Test method EN 16523-1:2015+A1:2018) <table><thead><tr><th>Chemical</th><th>Level</th></tr></thead><tbody><tr><td>40% Sodium Hydroxide (K)</td><td>6</td></tr></tbody></table> Protection against micro-organism risks to EN ISO 374-5:2016 <table><tbody><tr><td>Bacteria and fungi (Test method EN ISO 374-2:2019)</td><td>Pass</td></tr><tr><td>Viruses (Test Method ISO 16604:2004)</td><td>Pass</td></tr></tbody></table> General requirements for gloves to EN ISO 21420:2020 <table><tbody><tr><td>Dexterity:</td><td>Level 5</td></tr><tr><td>pH:</td><td>Pass</td></tr><tr><td>Size Range:</td><td>5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9</td></tr></tbody></table>	Chemical	Level	40% Sodium Hydroxide (K)	6	Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass	Viruses (Test Method ISO 16604:2004)	Pass	Dexterity:	Level 5	pH:	Pass	Size Range:	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9
Chemical	Level														
40% Sodium Hydroxide (K)	6														
Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass														
Viruses (Test Method ISO 16604:2004)	Pass														
Dexterity:	Level 5														
pH:	Pass														
Size Range:	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9														

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Page: 7 of 23

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EU Type Examination Certificate

No. CE 699813

Model: Biogel® Surgeons

Product Code: S961XX

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

Description: A sterile, powder-free, transparent natural rubber latex surgical overglove with polymeric inner surface treatment to assist donning. The glove is anatomically shaped, has straight fingers.

Performance: **Resistance to penetration to EN ISO 374-2:2019**

Performance Level 3

Resistance to degradation to EN ISO 374-4:2019

Tested for all chemicals listed below.

Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018

Type C Chemical protection (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6

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

Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

General requirements for gloves to EN ISO 21420:2020

Dexterity: Level 5

pH: Pass

Size Range: 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9

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Expiry Date: 2024-02-05

Page: 8 of 23

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EU Type Examination Certificate

No. CE 699813

Model: Biogel® PI UltraTouch®

Product Code: S409XX

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 is anatomically shaped, has curved fingers.

Performance: **Resistance to penetration to EN ISO 374-2:2019**

Performance Level 3

Resistance to degradation to EN ISO 374-4:2019

Tested for all chemicals listed below.

Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018

Type B Chemical protection (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6
30% Hydrogen Peroxide (P)	6
37% Formaldehyde (T)	6

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

Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

General requirements for gloves to EN ISO 21420:2020

Dexterity: Level 5

pH: Pass

Size Range: 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9

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Expiry Date: 2024-02-05

Page: 9 of 23

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EU Type Examination Certificate

No. CE 699813

Model: Biogel PI Indicator® Underglove

Product Code: S416XX

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 is anatomically shaped, has curved fingers.

Performance: **Resistance to penetration to EN ISO 374-2:2019**

Performance Level 3

Resistance to degradation to EN ISO 374-4:2019

Tested for all chemicals listed below.

Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018

Type B Chemical protection (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6
30% Hydrogen Peroxide (P)	6
37% Formaldehyde (T)	6

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

Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

General requirements for gloves to EN ISO 21420:2020

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

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Page: 10 of 23

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EU Type Examination Certificate

No. CE 699813

Model: **Biogel PI Indicator® System**

Product Code: **S414XX**

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: 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 penetration to EN ISO 374-2:2019**

Performance Level 3

Resistance to degradation to EN ISO 374-4:2019

Tested for all chemicals listed below.

Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018

Type B Chemical protection (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6
30% Hydrogen Peroxide (P)	6
37% Formaldehyde (T)	6

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

Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

General requirements for gloves to EN ISO 21420:2020

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

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Page: 11 of 23

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EU Type Examination Certificate

No. CE 699813

Model: Biogel Eclipse®

Product Code: S751XX

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

Description: A sterile, powder-free, transparent natural rubber latex surgical overglove with polymeric inner surface treatment to assist donning. The glove is anatomically shaped, has curved fingers.

Performance: **Resistance to penetration to EN ISO 374-2:2019**

Performance Level 3

Resistance to degradation to EN ISO 374-4:2019

Tested for all chemicals listed below.

Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018

Type C Chemical protection (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6

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

Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

General requirements for gloves to EN ISO 21420:2020

Dexterity: Level 5

pH: Pass

Size Range: 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9

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Page: 12 of 23

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No. CE 699813

Model: Biogel Eclipse® Indicator® Underglove

Product Code: S732XX

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

Description: A sterile, powder-free, green natural rubber latex surgical underglove with polymeric inner surface treatment to assist donning. The glove is anatomically shaped, has curved fingers.

Performance: **Resistance to penetration to EN ISO 374-2:2019**

Performance Level 3

Resistance to degradation to EN ISO 374-4:2019

Tested for all chemicals listed below.

Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018

Type C Chemical protection (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6

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

Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

General requirements for gloves to EN ISO 21420:2020

Dexterity: Level 5

pH: Pass

Size Range: 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9

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Page: 13 of 23

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Model: Biogel Eclipse® Indicator® System

Product Code: S607XX

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

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 penetration to EN ISO 374-2:2019**

Performance Level 3

Resistance to degradation to EN ISO 374-4:2019

Tested for all chemicals listed below.

Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018

Type C Chemical protection (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6

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

Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

General requirements for gloves to EN ISO 21420:2020

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

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Expiry Date: 2024-02-05

Page: 14 of 23

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EU Type Examination Certificate

No. CE 699813

Model: Biogel® Super-Sensitive

Product Code: S825XX

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

Description: A sterile, powder-free, transparent natural rubber latex surgical overglove with polymeric inner surface treatment to assist donning. The glove is anatomically shaped, has curved fingers.

Performance: **Resistance to penetration to EN ISO 374-2:2019**

Performance Level 3

Resistance to degradation to EN ISO 374-4:2019

Tested for all chemicals listed below.

Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018

Type C Chemical protection (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6

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

Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

General requirements for gloves to EN ISO 21420:2020

Dexterity: Level 5

pH: Pass

Size Range: 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9

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Latest Issue: 2021-11-02

Effective Date: 2021-11-02

Expiry Date: 2024-02-05

Page: 15 of 23

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EU Type Examination Certificate

No. CE 699813

Model: Biogel® Indicator® System

Product Code: S842XX

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

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 penetration to EN ISO 374-2:2019**

Performance Level 3

Resistance to degradation to EN ISO 374-4:2019

Tested for all chemicals listed below.

Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018

Type C Chemical protection (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6

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

Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

General requirements for gloves to EN ISO 21420:2020

Dexterity: Level 5

pH: Pass

Size Range: 5.5, 6, 6.5, 7, 7.5, 8, 8.5

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Expiry Date: 2024-02-05

Page: 16 of 23

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EU Type Examination Certificate

No. CE 699813

Model: Biogel® PI Micro

Product Code: S485XX

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. The glove is anatomically shaped, has curved fingers.

Performance: **Resistance to penetration to EN ISO 374-2:2019**

Performance Level 3

Resistance to degradation to EN ISO 374-4:2019

Tested for all chemicals listed below.

Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018

Type B Chemical protection (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6
30% Hydrogen Peroxide (P)	6
37% Formaldehyde (T)	6

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

Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

General requirements for gloves to EN ISO 21420:2020

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

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Latest Issue: 2021-11-02

Effective Date: 2021-11-02

Expiry Date: 2024-02-05

Page: 17 of 23

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EU Type Examination Certificate

No. CE 699813

Model: Biogel® PI Micro Indicator® Underglove

Product Code: S489XX

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. The glove is anatomically shaped, has curved fingers.

Performance: **Resistance to penetration to EN ISO 374-2:2019**

Performance Level 3

Resistance to degradation to EN ISO 374-4:2019

Tested for all chemicals listed below.

Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018

Type B Chemical protection (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6
30% Hydrogen Peroxide (P)	6
37% Formaldehyde (T)	6

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

Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

General requirements for gloves to EN ISO 21420:2020

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

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Expiry Date: 2024-02-05

Page: 18 of 23

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EU Type Examination Certificate

No. CE 699813

Model: Biogel® PI Micro Indicator® System

Product Code: S483XX

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: 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 penetration to EN ISO 374-2:2019**

Performance Level 3

Resistance to degradation to EN ISO 374-4:2019

Tested for all chemicals listed below.

Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018

Type B Chemical protection (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6
30% Hydrogen Peroxide (P)	6
37% Formaldehyde (T)	6

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

Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

General requirements for gloves to EN ISO 21420:2020

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

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Page: 19 of 23

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EU Type Examination Certificate

No. CE 699813

Model: Biogel® PI UltraTouch® S

Product Code: S455XX

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 is anatomically shaped, has curved fingers.

Performance: **Resistance to penetration to EN ISO 374-2:2019**

Performance Level 3

Resistance to degradation to EN ISO 374-4:2019

Tested for all chemicals listed below.

Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018

Type C Chemical protection (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6

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

Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass
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Viruses (Test Method ISO 16604:2004)	Pass
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General requirements for gloves to EN ISO 21420:2020

Dexterity: Level 5

pH: Pass

Size Range: 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9

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Page: 20 of 23

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EU Type Examination Certificate

No. CE 699813

Model: Biogel® PI UltraTouch® S Indicator® Underglove

Product Code: S459XX

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 is anatomically shaped, has curved fingers.

Performance: **Resistance to penetration to EN ISO 374-2:2019**

Performance Level 3

Resistance to degradation to EN ISO 374-4:2019

Tested for all chemicals listed below.

Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018

Type C Chemical protection (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6

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

Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

General requirements for gloves to EN ISO 21420:2020

Dexterity: Level 5

pH: Pass

Size Range: 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9

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Page: 21 of 23

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EU Type Examination Certificate

No. CE 699813

Model: Biogel® PI UltraTouch® S Indicator® System

Product Code: S453XX

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: 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 penetration to EN ISO 374-2:2019**

Performance Level 3

Resistance to degradation to EN ISO 374-4:2019

Tested for all chemicals listed below.

Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018

Type C Chemical protection (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6

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

Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

General requirements for gloves to EN ISO 21420:2020

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

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Expiry Date: 2024-02-05

Page: 22 of 23

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EU Type Examination Certificate

No. CE 699813

Certificate Administration Details

Technical File Reference: PPE Technical File - Dual Certified 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
November 2021	Amendment to include revised standard EN ISO 21420:2020, additional chemical claims, and removal of S33509 product.	2797:21:3423926

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: 2021-11-02

Effective Date: 2021-11-02

Expiry Date: 2024-02-05

Page: 23 of 23

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