

EC 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 577004

In respect of:

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

On the basis of our examination, under the requirements of Council Directive 89/686/EEC "Personal Protective Equipment" Article 10, EC Type-Examination

For and on behalf of BSI, a Notified
Body for the above Directive
(Notified Body Number 0086):



Gary Fenton, Global Product Certification Director

First Issued: 30/11/2011

Latest Issue: 21/02/2017

EC Type Examination Certificate

No. CE 577004

Product Specification

Models: **Biogel® Skinsense® S509**
Biogel® NeoTech S44509 (formerly Skinsense®)

Product Codes: **S509XX; S44509XX**

Classification: Protective gloves for use against microorganisms 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.

Performance: **Resistance to penetration to EN 374-2:2014**
Performance Level 3
Resistance to chemical permeation to EN 374-1:2003 (Test method EN 374-3:2003)
Waterproof gloves with Low Chemical Protection:

Chemical	Level
Sodium Hydroxide 40% (K)	6
96% Sulphuric acid (L)	2

Mechanical Hazards to EN 388:2003

Abrasion resistance Level 0
Blade cut resistance Level 0
Tear resistance Level 0
Puncture resistance Level 0

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

Dexterity: Level 5

Size Range: 5½, 6, 6½, 7, 7½, 8, 8½, 9

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Product Specification (continued)

Model: Biogel® Skinsense® Indicator Underglove

Product Code: S406XX

Classification: Protective gloves for use against microorganisms 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 underglove with polymeric inner surface treatment to assist donning. The glove provides a barrier to protect against cross-infection.

Performance: **Resistance to penetration to EN 374-2:2014**

Performance Level 3

Resistance to chemical permeation to EN 374-1:2003 (Test method EN 374-3:2003)

Waterproof gloves with Low Chemical Protection

Chemical	Level
Sodium Hydroxide 40% (K)	6
96% Sulphuric acid (L)	2

Mechanical Hazards to EN 388:2003

Abrasion resistance Level 0

Blade cut resistance Level 0

Tear resistance Level 0

Puncture resistance Level 0

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

Dexterity: Level 5

Size Range: 5½, 6, 6½, 7, 7½, 8, 8½, 9

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Product Specification (continued)

Model: Biogel® Skinsense® Indicator System

Product Code: S288XX

Classification: Protective gloves for use against specific chemical and microorganisms hazards. 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 374-2:2014**

Performance Level 3

Resistance to chemical permeation to EN 374-1:2003

(Test method EN 374-3:2003)

Chemical

Methanol (A)

Sodium Hydroxide 40% (K)

96% Sulphuric acid (L)

Level

3

6

5

Mechanical Hazards to EN 388:2003

Abrasion resistance Level 0

Blade cut resistance Level 0

Tear resistance Level 0

Puncture resistance Level 0

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

Dexterity: Level 5

Size Range: 5½, 6, 6½, 7, 7½, 8, 8½

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Product Specification (continued)

Models: **Biogel® Surgeons**
Biogel® Tech

Product Codes: **S828XX; S822XX; S44822XX**

Classification: Protective gloves for use against microorganisms 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.

Performance: **Resistance to penetration to EN 374-2:2014**
Performance Level 3
Resistance to chemical permeation to EN 374-1:2003
Waterproof gloves with Low Chemical Protection

Mechanical Hazards to EN 388:2003

Abrasion resistance Level 0
Blade cut resistance Level 0
Tear resistance Level 0
Puncture resistance Level 0

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

Dexterity: Level 5
Protein Level: Extractable protein content (EN 455-3): < 50 µg/g
Size Range: 5½, 6, 6½, 7, 7½, 8, 8½, 9

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Product Specification (continued)

Model: **Biogel® Surgeons**
Biogel® Tech

Product Codes: **S965XX; S961XX; S44961XX**

Classification: Protective gloves for use against microorganisms 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.

Performance: **Resistance to penetration to EN 374-2:2014**
Performance Level 3
Resistance to chemical permeation to EN 374-1:2003
Waterproof gloves with Low Chemical Protection

Mechanical Hazards to EN 388:2003

Abrasion resistance Level 0
Blade cut resistance Level 0
Tear resistance Level 0
Puncture resistance Level 0

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

Dexterity: Level 5
Protein Level: Extractable protein content (EN 455-3): < 50 µg/g
Size Range: 5½, 6, 6½, 7, 7½, 8, 8½, 9

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Product Specification (continued)

Model:	Biogel® Ultratouch S409 or S44431 Biogel® PI Tech S44409 (formerly Ultratouch)
Product Codes:	S409XX or S44409XX or S44431XX
Classification:	Protective gloves for use against microorganisms 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.
Performance:	Resistance to penetration to EN 374-2:2014 Performance Level 3 Resistance to chemical permeation to EN 374-1:2003 Waterproof gloves with Low Chemical Protection Mechanical Hazards to EN 388:2003 Abrasion resistance Level 0 Blade cut resistance Level 0 Tear resistance Level 0 Puncture resistance Level 0 General requirements for gloves to EN 420:2003+A1:2009
Dexterity:	Level 5
Size Range:	5 1/2, 6, 6 1/2, 7, 7 1/2, 8, 8 1/2, 9

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Product Specification (continued)

Model:	Biogel® PI Indicator Underglove
Product Codes:	S416XX or S44416XX
Classification:	Protective gloves for use against microorganisms 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.
Performance:	Resistance to penetration to EN 374-2:2014 Performance Level 3 Resistance to chemical permeation to EN 374-1:2003 Waterproof gloves with Low Chemical Protection Mechanical Hazards to EN 388:2003 Abrasion resistance Level 0 Blade cut resistance Level 0 Tear resistance Level 0 Puncture resistance Level 0 General requirements for gloves to EN 420:2003+A1:2009
Dexterity:	Level 5
Size Range:	5 ½, 6, 6 ½, 7, 7½, 8, 8½, 9

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Product Specification (continued)

Model: Biogel® PI Indicator System

Product Code: S414XX

Classification: Protective gloves for use against specific chemical and microorganisms hazards. 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 374-2:2014**
Performance Level 3

Resistance to chemical permeation to EN 374-1:2003 (Test method EN 374-3:2003)

Waterproof gloves with Low Chemical Protection:

Chemical	Level
Sodium Hydroxide 40% (K)	6
96% Sulphuric acid (L)	2

Mechanical Hazards to EN 388:2003

Abrasion resistance Level 0

Blade cut resistance Level 0

Tear resistance Level 0

Puncture resistance Level 0

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

Dexterity: Level 5

Size Range: 5½, 6, 6½, 7, 7½, 8, 8½, 9

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Product Specification (continued)

Model: Biogel® Eclipse

Product Code: S751XX

Classification: Protective gloves for use against microorganisms and general applications. Designed for single use 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 provides a barrier to protect against cross-infection.

Performance: **Resistance to penetration to EN 374-2:2014**
Performance Level 3
Resistance to chemical permeation to EN 374-1:2003
Waterproof gloves with Low Chemical Protection

Mechanical Hazards to EN 388:2003

Abrasion resistance Level 0
Blade cut resistance Level 0
Tear resistance Level 0
Puncture resistance Level 0

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

Dexterity: Level 5
Protein Level: Extractable protein content (EN 455-3): <50 µg/g
Size Range: 5 ½, 6, 6 ½, 7, 7½, 8, 8½, 9

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Product Specification (continued)

Model:	Biogel® Eclipse Indicator Underglove
Product Code:	S732XX
Classification:	Protective gloves for use against microorganisms and general applications. Designed for single use 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 provides a barrier to protect against cross-infection.
Performance:	Resistance to penetration to EN 374-2:2014 Performance Level 3 Resistance to chemical permeation to EN 374-1:2003 Waterproof gloves with Low Chemical Protection Mechanical Hazards to EN 388:2003 Abrasion resistance Level 0 Blade cut resistance Level 0 Tear resistance Level 0 Puncture resistance Level 0 General requirements for gloves to EN 420:2003+A1:2009
Dexterity:	Level 5
Protein Level:	Extractable protein content (EN 455-3): <50 µg/g
Size Range:	5½, 6, 6½, 7, 7½, 8, 8½, 9

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Product Specification (continued)

Model: Biogel® Eclipse Indicator System

Product Code: S607XX

Classification: Protective gloves for use against microorganisms and general applications. Designed for single use 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 374-2:2014**
Performance Level 3

Resistance to chemical permeation to EN 374-1:2003 (Test method EN 374-3:2003)

Waterproof gloves with Low Chemical Protection:

Chemical	Level
Sodium Hydroxide 40% (K)	6
96% Sulphuric acid (L)	1

Mechanical Hazards to EN 388:2003

Abrasion resistance Level 0

Blade cut resistance Level 0

Tear resistance Level 0

Puncture resistance Level 0

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

Dexterity: Level 5

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

Size Range: 5½, 6, 6½, 7, 7½, 8, 8½, 9

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Product Specification (continued)

Model: Biogel® Super Sensitive

Product Code: S825XX

Classification: Protective gloves for use against microorganisms and general applications. Designed for single use 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 provides a barrier to protect against cross-infection.

Performance: **Resistance to penetration to EN 374-2:2014**

Performance Level 3

Resistance to chemical permeation to EN 374-1:2003

Waterproof gloves with Low Chemical Protection

Mechanical Hazards to EN 388:2003

Abrasion resistance Level 0

Blade cut resistance Level 0

Tear resistance Level 0

Puncture resistance Level 0

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

Dexterity: Level 5

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

Size Range: 5½, 6, 6½, 7, 7½, 8, 8½, 9

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Product Specification (continued)

Model: Biogel® Super Sensitive Indicator System

Product Code: S842XX

Classification: Protective gloves for use against microorganisms and general applications. Designed for single use 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 374-2:2014**
Performance Level 3

Resistance to chemical permeation to EN 374-1:2003 (Test method EN 374-3:2003)

Waterproof gloves with Low Chemical Protection:

Chemical	Level
Sodium Hydroxide 40% (K)	6
96% Sulphuric acid (L)	2

Mechanical Hazards to EN 388:2003

Abrasion resistance Level 0

Blade cut resistance Level 0

Tear resistance Level 0

Puncture resistance Level 0

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

Dexterity: Level 5

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

Size Range: 5½, 6, 6½, 7, 7½, 8, 8½, 9

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Product Specification (continued)

Model: Biogel® Diagnostic S20X

Product Code: 565X

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

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

Performance: **Resistance to penetration to EN 374-2:2014**
Performance Level 3

Resistance to chemical permeation to EN 374-1:2003
Waterproof gloves with Low Chemical Protection.

Mechanical Hazards to EN 388:2003
Abrasion resistance Level 0
Blade cut resistance Level 0
Tear resistance Level 0
Puncture resistance Level 0

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

Dexterity: Level 5

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

Size Range: 5½, 6, 6½, 7, 7½, 8, 8½, 9

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Product Specification (continued)

Model: Biogel® Diagnostic S303

Product Code: 303XX

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

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

Performance: **Resistance to penetration to EN 374-2:2014**
Performance Level 3

Resistance to chemical permeation to EN 374-1:2003
Waterproof gloves with Low Chemical Protection.

Mechanical Hazards to EN 388:2003
Abrasion resistance Level 0
Blade cut resistance Level 0
Tear resistance Level 0
Puncture resistance Level 0

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

Dexterity: Level 5

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

Size Range: 5½, 6, 6½, 7, 7½, 8, 8½, 9

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Product Specification (continued)

Model: Biogel® Skinsense® (non-sterile)

Product Code: S33509XX;

Classification: Protective gloves for use against microorganisms 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, 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 penetration to EN 374-2:2014**
Performance Level 3
Resistance to chemical permeation to EN 374-1:2003 (Test method EN 374-3:2003)
Waterproof gloves with Low Chemical Protection:

Chemical	Level
Sodium Hydroxide 40% (K)	6
96% Sulphuric acid (L)	2

Mechanical Hazards to EN 388:2003

Abrasion resistance Level 0
Blade cut resistance Level 0
Tear resistance Level 0
Puncture resistance Level 0

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

Dexterity: Level 5

Size Range: 5½, 6, 6½, 7, 7½, 8, 8½, 9

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Product Specification (continued)

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

Product Code: S33406XX

Classification: Protective gloves for use against microorganisms 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, 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 penetration to EN 374-2:2014**

Performance Level 3

Resistance to chemical permeation to EN 374-1:2003 (Test method EN 374-3:2003)

Waterproof gloves with Low Chemical Protection:

Chemical	Level
Sodium Hydroxide 40% (K)	6
96% Sulphuric acid (L)	2

Mechanical Hazards to EN 388:2003

Abrasion resistance Level 0

Blade cut resistance Level 0

Tear resistance Level 0

Puncture resistance Level 0

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

Dexterity: Level 5

Size Range: 5½, 6, 6½, 7, 7½, 8, 8½, 9

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Product Specification (continued)

Model: Biogel® Micro

Product Code: 885XX

Classification: Protective gloves for use against microorganisms and general applications. Designed for single use 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 provides a barrier to protect against cross-infection.

Performance: **Resistance to penetration to EN 374-2:2003**
Performance Level 3
Resistance to chemical permeation to EN 374-1:2003 (Test method EN 374-3:2003)
Waterproof gloves with Low Chemical Protection:

Chemical	Level
Sodium Hydroxide 40% (K)	6
96% Sulphuric acid (L)	1

Mechanical Hazards to EN 388:2003

Abrasion resistance Level 0
Blade cut resistance Level 0
Tear resistance Level 0
Puncture resistance Level 0

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

Dexterity: Level 5

Size Range: 5½, 6, 6½, 7, 7½, 8, 8½, 9

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EC Type Examination Certificate

No. CE 577004

Product Specification (continued)

Model: Biogel® Micro Indicator Underglove

Product Code: 889XX

Classification: Protective gloves for use against microorganisms and general applications. Designed for single use 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 provides a barrier to protect against cross-infection.

Performance: **Resistance to penetration to EN 374-2:2003**

Performance Level 3

Resistance to chemical permeation to EN 374-1:2003 (Test method EN 374-3:2003)

Waterproof gloves with Low Chemical Protection:

Chemical	Level
Sodium Hydroxide 40% (K)	6
96% Sulphuric acid (L)	1

Mechanical Hazards to EN 388:2003

Abrasion resistance Level 0

Blade cut resistance Level 0

Tear resistance Level 0

Puncture resistance Level 0

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

Dexterity: Level 5

Size Range: 5½, 6, 6½, 7, 7½, 8, 8½, 9

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EC Type Examination Certificate

No. CE 577004

Product Specification (continued)

Model: Biogel® Micro Indicator System

Product Code: 883XX

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

Description: The glove system consists of two products: underglove 889XX and overglove 885XX, both are made as sterile, powder-free, natural rubber latex gloves with polymeric inner surface treatment. The glove system 883XX is primarily used to provide a double barrier against cross-infections and for the purpose of puncture indication.

Performance: **Resistance to penetration to EN 374-2:2003**

Performance Level 3

Resistance to chemical permeation to EN 374-1:2003 (Test method EN 374-3:2003)

Waterproof gloves with Low Chemical Protection:

Chemical	Level
Sodium Hydroxide 40% (K)	6
96% Sulphuric acid (L)	1

Mechanical Hazards to EN 388:2003

Abrasion resistance Level 0

Blade cut resistance Level 0

Tear resistance Level 0

Puncture resistance Level 0

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

Dexterity: Level 5

Size Range: 5½, 6, 6½, 7, 7½, 8, 8½

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EC Type Examination Certificate

No. CE 577004

Product Specification (continued)

Model: Biogel® PI Micro

Product Code: 485XX

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

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

Performance: **Resistance to penetration to EN 374-2:2003**
Performance Level 3
Resistance to chemical permeation to EN 374-1:2003 (Test method EN 16523-1:2015)
Waterproof gloves with Low Chemical Protection:

Chemical	Level
Sodium Hydroxide 40% (K)	6
96% Sulphuric acid (L)	1

Mechanical Hazards to EN 388:2003

Abrasion resistance Level 0
Blade cut resistance Level 0
Tear resistance Level 0
Puncture resistance Level 0

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

Dexterity: Level 5

Size Range: 5½, 6, 6½, 7, 7½, 8, 8½, 9

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EC Type Examination Certificate

No. CE 577004

Product Specification (continued)

Model: Biogel® PI Micro Indicator Underglove

Product Code: 489XX

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

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

Performance: **Resistance to penetration to EN 374-2:2003**

Performance Level 3

Resistance to chemical permeation to EN 374-1:2003 (Test method EN 16523-1:2015)

Waterproof gloves with Low Chemical Protection:

Chemical	Level
Sodium Hydroxide 40% (K)	6
96% Sulphuric acid (L)	1

Mechanical Hazards to EN 388:2003

Abrasion resistance Level 0

Blade cut resistance Level 0

Tear resistance Level 0

Puncture resistance Level 0

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

Dexterity: Level 5

Size Range: 5½, 6, 6½, 7, 7½, 8, 8½, 9

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EC Type Examination Certificate

No. CE 577004

Product Specification (continued)

Model: Biogel® PI Micro Indicator System

Product Code: 483XX

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

Description: The glove system consists of two products: underglove 489XX and overglove 485XX, both are made as sterile, powder-free, polyisoprene gloves. The glove system 483XX is primarily used to provide a double barrier against cross-infections and for the purpose of puncture indication.

Performance: **Resistance to penetration to EN 374-2:2003**

Performance Level 3

Resistance to chemical permeation to EN 374-1:2003 (Test method EN 16523-1:2015)

Waterproof gloves with Low Chemical Protection:

Chemical	Level
Sodium Hydroxide 40% (K)	6
96% Sulphuric acid (L)	1

Mechanical Hazards to EN 388:2003

Abrasion resistance Level 0

Blade cut resistance Level 0

Tear resistance Level 0

Puncture resistance Level 0

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

Dexterity: Level 5

Size Range: 5½, 6, 6½, 7, 7½, 8, 8½

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EC Type Examination Certificate

No. CE 577004

Certificate Administration Details

Technical File Reference: Biogel® – PPE Technical File Mölnlycke.

Certificate Amendment Record

Issue date	Comments	BSI Project Number
November 2011	First issue.	0086:11:7702069
March 2014	Addition of new models Biogel® Surgeons S828 and S965. Addition of chemical protection and puncture resistance level 1 for Biogel® Indicator System S288.	0086:14:8120008
December 2014	Addition of Biogel® PI gloves, models: S409, S44409, S44431, S416, S44416 and S414.	0086:14:8243610
February 2015	Addition of alternative brand name: Biogel® Tech S961; S44961; S822; S44822. Addition of Biogel® Eclipse: S732, S751, S607 and Biogel® Super Sensitive S825, S842.	0086:15:8285997
April 2015	Addition of new models: Biogel® Diagnostic S20X and Biogel® Diagnostic S303X, addition of alternative product code S44509XX. Update to standard EN 374-2:2014.	0086:15:8320501
October 2015	Addition of new models: Biogel® Skinsense (non-sterile) S33406 and S33509. Change of chemical protection level for model S288 to level 3. Removal of puncture resistance claim for glove systems.	0086:15:8420473
June 2016	Addition of new models: Biogel® Micro 885XX, Biogel® Micro Indicator Underglove 889XX and Biogel® Micro Indicator System 883XX.	0086:16:8548421
September 2016	Addition of new models: Biogel® PI Micro 485XX; Biogel® PI Micro Indicator Underglove 489XX; Biogel® PI Micro Sytem 483XX. Change of model names for Biogel® PI Tech 44409XX and Biogel® NeoTech 44509XX.	0086:16:8577184
February 2017	Change of chemical protection level for models: S33509, S509, S44509, S33406 and S406.	0086:17:8675056

Note: The Certificate holder is responsible for keeping the Notified Body advised of changes to any aspect of the overall process used in the manufacture of the product.

Monitoring of manufactured PPE

The EC Quality of Production by Monitoring requirements, Article 11A, for the product are referenced in BSI issued Certificate number CE 578631.

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