

EU Type Examination Certificate

This is to certify that:

Medline Industries, LP
Three Lake Drive
Northfield
Illinois
60093
USA

Holds Certificate Number:

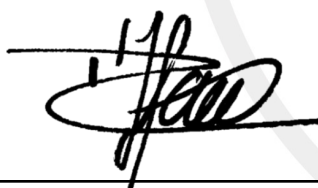
CE 689807

In respect of:

Model Sensicare PI Evolution Disposable Surgical Gloves
To EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016

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 Hagenaaers, Managing Director

First Issued: 2018-07-31
Latest Issue: 2022-04-11

Effective Date: 2022-04-11
Expiry Date: 2023-07-31

Page: 1 of 5



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EU Type Examination Certificate

No. CE 689807

Product Specification

Model:	Sensicare PI Evolution Surgical Gloves.
Classification:	Protective gloves against dangerous chemicals and micro-organisms.
Description:	Sterile, single use, five fingered, powder-free synthetic polyisoprene gloves with a synthetic polymer coating. Gloves have a tapered beaded cuff and are coloured white.
Size range:	5.5 to 9 in half sizes.
Product Codes:	MSG9555, MSG9560, MSG9565, MSG9570, MSG9575, MSG9580, MSG9585, MSG9590
PPE Category:	Category III - Complex.

Technical Specification: Type Examination for all PPE models listed in this certificate is conducted to Annex II of the Regulation (EU) 2016/425 and based on the following European Standards:

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

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.

EN ISO 374-4:2019 – Protective gloves against dangerous 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-organism risks.

EN 16523-1:2015+A1:2018 - Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to permeation by chemicals.

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.

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Page: 2 of 5

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Performance

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

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

EN ISO 374-2:2019 – Protection against penetration by micro-organisms. Determination of resistance to penetration.

Characteristic	Performance
Water Leak	Pass
Air Leak	Pass

EN ISO 374-4:2019 – Resistance to degradation

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)

Code Letter	Chemical	Permeation Level
K	40% Sodium Hydroxide	4
L	96% Sulfuric Acid	2
M	65% Nitric Acid	4
O	25% Ammonium Hydroxide	1
P	30% Hydrogen Peroxide	4
S	40% Hydrofluoric Acid	4
T	37% Formaldehyde	4

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

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Page: 3 of 5

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

Pass
Pass



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Page: 4 of 5

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Certificate Administration Details

Technical File Reference: 'Document No. CEP2009005 MEDLINE PPE Surgical Gloves, Rev 09'

Certificate Administration Record and BSI internal Technical File Review reference

Issue date	Comments	BSI Project Ref.
July 2018	Transition of certificate to Module B under PPE Regulation (EU) 425/2016, formerly Article 10 of the PPE Directive 89/686/EEC under BSI issued certificate CE 650294	0086:18:8953357
November 2020	Addition of chemicals Sulfuric Acid, Nitric Acid, Ammonium Hydroxide and Hydrofluoric Acid. Change to type A. Sodium Hydroxide, Hydrogen Peroxide and Formaldehyde claimed permeation levels reduced. Change of manufacturing location and minor amendments	2797:20:3172025
April 2022	Company name change. Standards update.	2797:22:3582155

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 validity of the Certificate for the products is also dependent on the maintenance of the 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 651845.

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Page: 5 of 5

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