

# EU Type Examination Certificate

This is to certify that:

Medline Industries, Inc.  
Three Lakes Drive  
Northfield  
Illinois  
60093  
USA

Holds Certificate Number:

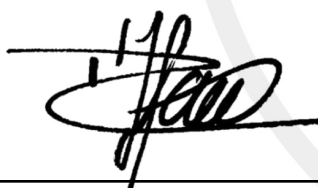
CE 689809

In respect of:

**Disposable Surgical Gloves to  
EN 420:2003+A1:2009, EN ISO 374-1:2016, and EN ISO 374-5:2016  
Model: Dermassure Green Surgical Gloves**

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: 2020-08-24

Effective Date: 2020-08-24

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## Product Specification

<b>Model:</b>	Dermassure Green Surgical Gloves.
<b>Classification:</b>	Protective gloves against dangerous chemicals and micro-organisms.
<b>Description:</b>	Sterile, single use, five fingered, powder-free synthetic polychloroprene gloves with a synthetic polymer coating. Gloves have a tapered beaded cuff and are coloured green.
<b>Size range:</b>	5.5 to 9 in half sizes.
<b>Product codes:</b>	MSG6555, MSG6560, MSG6565, MSG6570, MSG6575, MSG6580, MSG6585 and MSG6590
<b>PPE Category:</b>	Category III - Complex.
<b>Applicable Standards:</b>	<p>The following Harmonized European Standards:</p> <p>EN 420:2003+A1:2009 - Protective gloves. General requirements.</p> <p>EN ISO 374-1:2016 - Protective gloves against chemicals and micro-organisms. Terminology and performance requirements.</p> <p>EN 374-2:2014 - Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to penetration.</p> <p>EN 374-4:2013 – Protective gloves against chemicals and micro-organisms. Determination of resistance to degradation by chemicals.</p> <p>EN ISO 374-5:2016 – Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organism risks.</p> <p>EN 16523-1:2015 - Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to permeation by chemicals.</p> <p>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.</p>

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## Performance

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

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

### EN 374-2:2014 – Protection against penetration by micro-organisms. Determination of resistance to penetration.

Characteristic	Performance
Water Leak	Pass
Air Leak	Pass

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

Tested for all chemicals listed below.

### EN 16523-1:2015 Protective gloves against chemicals and micro-organisms. Determination of resistance of permeation by chemicals. Type A

Code Letter	Chemical	Permeation Level
A	Methanol	1
K	40% Sodium Hydroxide	4
L	96% Sulfuric Acid	3
O	25% Ammonium Hydroxide	2
P	30% Hydrogen Peroxide	4
S	40% Hydrofluoric Acid	4
T	37% Formaldehyde	4

### ISO16604:2004 Resistance to penetration by blood-borne pathogens

Pass

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## Certificate Administration Details

**Technical File Reference: 'Document No. CEP2009005 MEDLINE PPE Surgical Gloves, Rev 07'**

## 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 650296	0086:18:8953359
August 2020	Addition of chemicals Methanol, Sulfuric Acid, Ammonium Hydroxide and Hydrofluoric Acid. Product codes added. Sodium Hydroxide, Hydrogen Peroxide and Formaldehyde claimed permeation levels reduced	2797:20:9768464

## Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall process utilised in the manufacture of the products, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes

The requirements for internal production control, plus supervised product checks at random intervals are referenced in BSI issued Module CE Certificate Number CE 651845.

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

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