

EU Type Examination Certificate

This is to certify that:

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

Holds Certificate Number:


CE 689818

In respect of:

**Disposable Surgical Gloves to
EN 420:2003+A1:2009, EN 374-1:2016 and EN 374-5:2016
Model: Signature Latex Essential Surgical Gloves**

on the basis BSI carried out the relevant Type Examination procedure in accordance with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II.

For and on behalf of BSI:


Chris Lewis - Certification Director, Product Certification

First Issued: 2018-07-31

Latest Issue: 2018-07-31

Effective Date: 2018-07-31

Expiry Date: 2023-07-31

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Product Specification

Model:	Signature Latex Essential
Classification:	Protective gloves for use against dangerous chemicals and micro-organisms.
Description:	Natural rubber latex surgical gloves, powder free, sterile with chemical protection. The cuff design is tapered and beaded, available in cream colour.
Size range:	5.5 to 9 in half sizes.
Product Codes:	MSG5955, MSG5960, MSG5965, MSG5970, MSG5975, MSG5980, MSG5985, MSG5990
PPE Category:	Category III - Complex.
Applicable Standards:	<p>The following Harmonized European Standards:</p> <p>EN 420:2003+A1:2009 - Protective gloves. General requirements.</p> <p>EN 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 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>EN 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
pH value	Pass
Dexterity	Level 5
Length and Fit	Pass

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

Characteristic	Performance
Water 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 B

Code Letter	Chemical	Permeation Level
K	40% Sodium Hydroxide	6
P	30% Hydrogen Peroxide	6
T	37% Formaldehyde	6

EN 16604:2004 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

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 679906	0086:18:8953679

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 C2 Certificate Number CE 651845.

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

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