

EU Type Examination Certificate

This is to certify that:

Medline International France SAS
5 Rue Charles Lindbergh
Châteaubriant
44110
France

Holds Certificate Number:

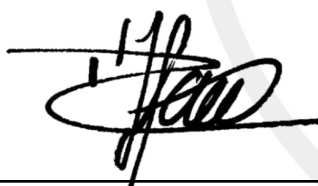
CE 723859

In respect of:

**Disposable Surgical Gloves to
EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018 and EN ISO 374-5:2016
Model: Sensicare Neoprene 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 Hagenaaars, Managing Director

First Issued: 2020-08-27

Latest Issue: 2021-02-12

Effective Date: 2021-02-12

Expiry Date: 2025-08-27

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Product Specification

Model:	Sensicare Neoprene Surgical Gloves.
Classification:	Protective gloves against dangerous chemicals and micro-organisms.
Description:	Sterile, single use, five fingered, powder-free synthetic polychloroprene gloves with a synthetic polymer coating. Gloves have a tapered beaded cuff and are coloured light brown.
Size range:	5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0.
Product codes:	MSG6355, MSG6360, MSG6365, MSG6370, MSG6375, MSG6380, MSG6385 and MSG6390
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 ISO 374-1:2016+A1:2018 - 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 374-4:2019 – 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+A1:2018 - 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 374-4:2019 – Resistance to degradation

Tested for all chemicals listed below.

EN 16523-1:2015+A1:2018 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
M	65% Nitric Acid	4
O	25% Ammonium Hydroxide	3
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 08'

Certificate Administration Record and BSI internal Technical File Review reference

Issue date	Comments	BSI Project Ref.
August 2020	Initial Issue	2797:20:3143362
February 2021	Change to type A	2797:21:3368103

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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