

EU Type Examination Certificate

This is to certify that:

Medline International France SAS
5 Rue Charles Lindbergh
Châteaubriant
44110
France

Holds Certificate Number:

CE 689806

In respect of:

**Disposable Examination Gloves to
EN 420:2003+A1:2009, EN ISO 374-1:2016 and EN ISO 374-5 :2016
Model: Sensicare Free/MDSFREE Series Nitrile Examination 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):

Previous Notified Body: BSI 0086

First Issued: 2018-08-13

Latest Issue: 2019-09-12



Drs. Dave Hagenaaars, Managing Director

Effective Date: 2019-09-12

Expiry Date: 2023-08-13

Page: 1 of 5



...making excellence a habit.™

EU Type Examination Certificate

No. CE 689806

Product Specification

| | |
|------------------------------|---|
| Model: | Sensicare Free/MDSFREE Series Examination Gloves. |
| Classification: | Protective gloves for use against dangerous chemicals and micro-organisms. |
| Description: | Non sterile, single use, five fingered, powder free Nitrile gloves. Gloves are blue coloured. |
| Size range: | Extra Small to Extra Large. |
| Product Codes: | MDSFREE-XS, MDSFREE-S, MDSFREE-M, MDSFREE-L, MDSFREE-XL |
| PPE Category: | Category III - Complex. |
| Applicable Standards: | The following Harmonized European Standards: EN 420:2003+A1:2009 - Protective gloves. General requirements. EN 374-1:2016 - Protective gloves against chemicals and micro-organisms - Terminology and performance requirements. EN 374-2:2014 - Protective gloves against dangerous chemicals and micro-organisms - Determination of resistance to penetration. EN 374-4:2013 – Protective gloves against chemicals and micro-organisms. Determination of resistance to degradation by chemicals. EN 374-5:2016 – Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organism risks. EN 16523-1:2015 - Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to permeation by chemicals. 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. |

First Issued: 2018-08-13

Latest Issue: 2019-09-12

Effective Date: 2019-09-12

Expiry Date: 2023-08-13

Page: 2 of 5

This certificate has been issued by and remains the property of BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands and should be returned immediately upon request.
To check its validity telephone +31 20 3460780. An electronic certificate can be authenticated [online](#).

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
A member of BSI Group of Companies.

EU Type Examination Certificate

No. CE 689806

Performance

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

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

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 C:

| Code Letter | Chemical | Permeation Level |
|-------------|----------------------|------------------|
| K | 40% Sodium Hydroxide | 6 |

EN 16604:2004 Resistance to penetration by blood-borne pathogens

Pass

First Issued: 2018-08-13

Latest Issue: 2019-09-12

Effective Date: 2019-09-12

Expiry Date: 2023-08-13

Page: 3 of 5

This certificate has been issued by and remains the property of BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands and should be returned immediately upon request.
To check its validity telephone +31 20 3460780. An electronic certificate can be authenticated [online](#).

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
A member of BSI Group of Companies.

EU Type Examination Certificate

No. CE 689806

Certificate Administration Details

Technical File Reference: Tech File No. 24

Certificate Administration Record and BSI internal Technical File Review reference

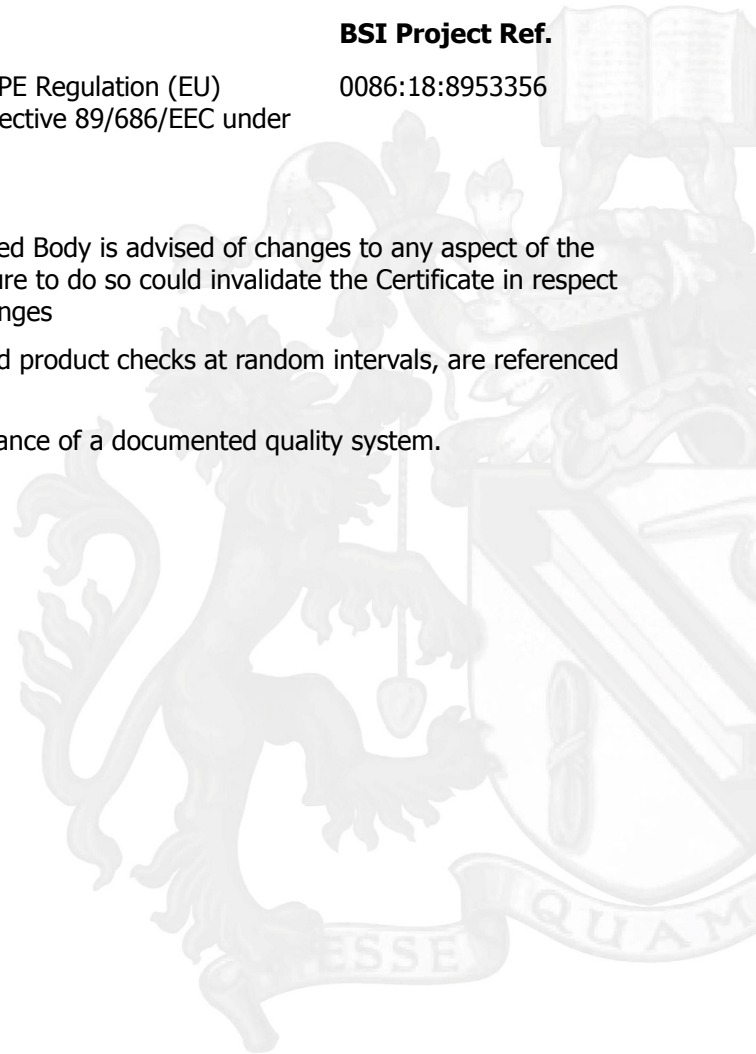
| Issue date | Comments | BSI Project Ref. |
|-------------|--|------------------|
| August 2018 | Transition of certificate to Module B under PPE Regulation (EU) 425/2016, formerly Article 10 of the PPE Directive 89/686/EEC under BSI issued certificate CE 668259 | 0086:18:8953356 |

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 653430.

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



First Issued: 2018-08-13

Latest Issue: 2019-09-12

Effective Date: 2019-09-12

Expiry Date: 2023-08-13

Page: 4 of 5

This certificate has been issued by and remains the property of BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands and should be returned immediately upon request.
To check its validity telephone +31 20 3460780. An electronic certificate can be authenticated [online](#).

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
A member of BSI Group of Companies.

EU Type Examination Certificate

No. CE 689806

Location

Medline International France SAS
5 Rue Charles Lindbergh
Châteaubriant
44110
France

Certified Activities

Disposable Examination Gloves to
EN 420:2003+A1:2009, EN ISO 374-1:2016 and EN ISO 374-
5 :2016
Model: Sensicare Free/MDSFREE Series Nitrile Examination
Gloves.



First Issued: 2018-08-13

Latest Issue: 2019-09-12

Effective Date: 2019-09-12

Expiry Date: 2023-08-13

Page: 5 of 5

This certificate has been issued by and remains the property of BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands and should be returned immediately upon request.
To check its validity telephone +31 20 3460780. An electronic certificate can be authenticated [online](#).

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
A member of BSI Group of Companies.