EU Type Examination Certificate

This is to certify that:

Medline International France SAS
5 Rue Charles Lindbergh
Châteaubriant
44110
France

Holds Certificate Number: CE 689805

In respect of:

Sensicare Pro Disposable Examination Gloves
To Technical Specification satisfying Annex II of PPE Regulation (EU) 2016/425 and utilizing standards: EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018 and 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):

Denelise L'Ecluse, Managing Director Assurance - Continental Europe

First Issued: 2018-08-13
Latest Issue: 2023-08-02

Effective Date: 2023-08-02
Expiry Date: 2028-08-12

PRODUCTS
RvA C 646

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Product Specification

Model:	Sensicare Pro/PRO400 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 with finger to wrist textured finish. Gloves are 400mm in length, blue coloured and have a beaded cuff. The protection area applies to both palm and cuff.
Size range:	6 (Extra Small), 7 (Small), 8 (Medium), 9 (Large), 10 (Extra Large)
Product Codes:	PRO400XS, PRO400S, PRO400M, PRO400L, PRO400XL
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 ISO 21420:2020 – 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. EN 388:2016+A1:2018 - Protective gloves against mechanical risks

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Performance

EN ISO 21420:2020 – General requirements:

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

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 B Chemical protection (Test method EN 16523-1:2015+A1:2018)

Code Letter	Chemical	Permeation Level
K	40% Sodium Hydroxide	4
P	30% Hydrogen Peroxide	4
T	37% Formaldehyde	4

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

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

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Performance (continued):

EN 388:2016+A1:2018- Mechanical risks

Characteristic	Performance
Abrasion	Level 1
Blade Cut	Level 0
Tear	Level 0
Puncture	Level 0
TDM Cut	X (not performed)

Certificate Administration Details

Technical File Reference: 'EU1-00004-F-00007, Technical File N° 24 Non-sterile Examination gloves.'

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 657599	0086:18:8953355
July 2019	Addition of EN 388:2016 mechanical properties	0086:19:9774284
November 2020	Sodium Hydroxide, Hydrogen Peroxide and Formaldehyde claimed permeation levels reduced.	2797:20:3169789
July 2021	Abrasion performance reduced to level 1	2797:21:3448382
May 2022	Certificate reissue- standards update.	2797:22:3637839
August 2023	Reissue due to 5-year certificate renewal under the PPE Regulation (EU) 2016/425 and standard update to EN ISO 21420. Removal of puncture resistance claim. Transition to Module D surveillance.	2797:23:3912373

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.

Monitoring of manufactured PPE

The validity of the Certificate for the products is also dependent on the maintenance of the EU Conformity to Type based on Internal Production Control plus supervised product checks at random intervals, Annex VII (Module C2) until the transition to continuous annual surveillance based on Quality Assurance of the Production Process, Annex VIII (Module D), which will supersede the former on the date of the certificate's release.

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