EU Type Examination Certificate

This is to certify that:

Medline International France SAS
5 Rue Charles Lindbergh
Châteaubriant
44110
France

Holds Certificate Number: CE 696795

In respect of:

Sensicare Silk and Sensicare Silk Cuff First 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: 2024-04-12

Effective Date: 2024-04-12
Expiry Date: 2028-08-12

PRODUCTS
RvA C 646

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EU Type Examination Certificate

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Product Specification

Model:	Sensicare Silk 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 have a beaded cuff and are blue coloured.
Size range:	6 (Extra Small), 7 (Small), 8 (Medium), 9 (Large), 10 (Extra Large).
Product Codes:	MDS9083, MDS9084, MDS9085, MDS9086, MDS9087
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.

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Performance

EN ISO 21420:2020 – General requirements:

Characteristic	Performance
pH	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 C Chemical protection (Test method EN 16523-1:2015+A1:2018)

Code Letter	Chemical	Permeation Level
K	40% Sodium Hydroxide	6

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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Product Specification (continued):

Model:	Sensicare Silk Series Cuff First 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 have a beaded cuff and are blue coloured. This product comes with Cuff First packaging technology allowing to dispense one glove at the time.
Size range:	6 (Extra Small), 7 (Small), 8 (Medium), 9 (Large), 10 (Extra Large).
Product Codes:	MDS9083CF, MDS9084CF, MDS9085CF, MDS9086CF, MDS9087CF
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.

Performance

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EN ISO 21420:2020 – General requirements:

Characteristic	Performance
pH	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 C Chemical protection (Test method EN 16523-1:2015+A1:2018)

Code Letter	Chemical	Permeation Level
K	40% Sodium Hydroxide	6

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

Certificate Administration Details

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

Certificate Administration Record and BSI internal Technical File Review reference

Issue date	Comments	BSI Project Ref.
August 2018	First Issue	0086:18:8997898
March 2022	Certificate reissue- standards update.	2797:22:3637882
August 2023	Reissue due to 5-year certificate renewal under the PPE Regulation (EU) 2016/425 and standard update to EN ISO 21420. Transition to Module D surveillance.	2797:2023:3912380
April 2024	Addition of Sensicare Silk Series Cuff First (MDS908xCF).	2797:24:30129004

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 Quality Assurance of the Production Process, Annex VIII (Module D), as referenced on BSI issued Certificate CE 787342.

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