Conformity to Type based on Quality Assurance of the Production Process

This is to certify that:

Medline International France SAS
5 Rue Charles Lindbergh
Châteaubriant
44110
France

Holds Certificate Number: CE 787342

In respect of:

For the manufacture of gloves to the standards specified on the continuation sheet.

on the basis that BSI carried out the quality assurance assessment under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex VIII (Module D)

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: 2023-08-31
Latest Issue: 2023-08-31

Effective Date: 2023-08-31
Expiry Date: 2028-08-30

PRODUCTS
RvA C 646

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.

Conformity to Type based on Quality Assurance of the Production Process

No. CE 787342

PPE Module B Certificate holding location:

Medline International France SAS
5 Rue Charles Lindbergh
Châteaubriant
44110
France

Manufacturing Sites:

Product manufactured at the locations and processes detailed in accordance with PPE Regulation (EU) 2016/425; Technical file 'EU1-00004-F-00007, Technical File N° 24 Non-sterile Examination gloves'; and BSI Module B certificates: CE 689803, CE 696796.

Technical Specifications:

The products covered by the scope of this Certificate conform to technical specification, meeting Essential Health and Safety Requirements of Annex II of the PPE Regulation 2016/425, utilizing the following standards:

Applicable standards	Product Type
EN 420:2003+A1:2009	Protective gloves. General requirements and test methods.
EN ISO 374-1:2016+A1:2018	Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.
EN ISO 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organism 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 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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Manufacturing Sites (continues):

Product manufactured at the locations and processes detailed in accordance with PPE Regulation (EU) 2016/425; Technical file 'EU1-00004-F-00007, Technical File N° 24 Non-sterile Examination gloves'; and BSI Module B certificates: CE 689800, CE 689806, CE 689805*, CE 696795, CE 689802, CE 689801, CE 689796, CE 714513, CE 696797, CE 689804, CE 708222, CE 739234.

Technical Specifications:

The products covered by the scope of this Certificate conform to technical specification, meeting Essential Health and Safety Requirements of Annex II of the PPE Regulation 2016/425, utilizing the following standards:

Applicable standards	Product Type
EN ISO 21420:2020	Protective gloves. General requirements and test methods.
EN ISO 374-1:2016+A1:2018	Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.
EN ISO 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organism 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 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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Certificate Administration Details

Issue Date	Comments	BSI Review No.
August 2023	First Issue to PPE Regulation (EU) 2016/425.	2797:23:3874805

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 validity of the Certificate is also dependent on the maintenance of an ISO 9001 quality system certified by a recognized certification organisation.

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