



Conformity to Type based on Internal Production Control plus supervised product checks at random intervals

This is to certify that:

Mölnlycke Health Care AB Gamlestadsvägen 3C Box 13080 Göteborg SE-402 52 Sweden

Holds Certificate Number:

CE 578631

In respect of:

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

on the basis that BSI carried out the supervised production checks at random intervals under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex VII (Module C2)

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Previous Notified Body: BSI 0086

First Issued: 2011-11-30 Latest Issue: 2019-09-12 Drs. Dave Hagenaars, Managing Director

Effective Date: 2019-09-12 Expiry Date: 2024-01-16

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...making excellence a habit."



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No. CE 578631

PPE Module B Certificate holding location:

Mölnlycke Health Care AB Gamlestadswagen 3C Box 13080 Göteborg SE-402 52 Sweden

Manufacturing Sites:

Mölnlycke Health Care Sdn Bhd Lot 9, Lorong Perusahaan 4 P.O. Box 52 Kulim Industrial Estate 09000 Kulim Kedah Malaysia

Mölnlycke Health Care Sdn Bhd Lot B5 & B6 Kawasan Perusahaan MIEL Batang Kali Phase II 44300 Batang Kali, Selangor Malaysia

Molnlycke Health Care Sdn. Bhd. Kawasan Perindustrian Kuala Ketil 09300 Kuala Ketil Kedah Malaysia

Product Specification

The gloves covered by the scope of this Module C2 certificate conform to the following standards:

Standard	Product Type	
EN 374-1:2016	Protective gloves against dangerous chemicals and micro-organisms. Part 1:Terminology and performance requirements for chemical risks.	
EN 374-2:2014	Protective gloves against dangerous chemicals and microorganisms. Determination of resistance to penetration.	
EN 16523-1:2015	Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to permeation by chemicals.	
BS EN 420:2003+A1:2009	Protective gloves. General requirements.	
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Certificate Administration Details

Certificate Amendment Record and BSI internal Review relating to this Certificate:

Issue date	Comments	BSI Review No.
January 2019	Transition of certificate to Module C2 under PPE Regulation (EU) 2016/425, formerly Article 11a of the PPE Directive 89/686/EEC.	0086:19:9690322

Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspects of the overall quality system utilized in the manufacture of the products. Failure to do so could invalidate the Certificate in respect of product manufactured after the introduction of such changes.

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Location **Certified Activities**

Mölnlycke Health Care AB Gamlestadsvägen 3C Box 13080 Göteborg SE-402 52 Sweden

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



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