

We, Mölnlycke Health Care, Gamlestadvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being exclusively responsible manufacturer for conformity of the device/s; declare that the devices listed in the attached schedule are in conformity with the provisions of Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: **Not applicable**

Trade name/ Product name:	<b>Shoe Covers</b>
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Product classification: **I**  
 MDR Classification Rule: **1**  
 Sterility: **Non-sterile**  
 Measuring function: **No**

This declaration is supported by a conformity assessment procedure in accordance with	
Annex/es:	<b>IV</b>
Common Specification:	<b>No CS is applicable</b>

Certificate number:	<b>Not Applicable</b>
Issued by:	<b>Not Applicable</b>
NB. For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.	

Mölnlycke Health Care issues this declaration in recognition of applied harmonised standards.

Signed for and on behalf of Mölnlycke Health Care AB

Place of Issue: Göteborg, Sweden

Date: **2021-04-23**                      Function: **Regulatory Affairs Director**

Name: **Christina Lewing**

Signature:



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**EU Declaration of Conformity  
according to MDR**

Document ID: PD-611697 Rev: 00

Title: Shoe Covers

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Intended Purpose: The product should be worn in situations where there is a risk that infectious agents can be transferred throughout the hospital.

**Product(s) covered by this declaration:**

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
359010	SHOE COVER	73324300000000097KH	15056 Shoe cover, non-conductive, non-sterile
359050	SHOE COVER	73324300000000097KH	15056 Shoe cover, non-conductive, non-sterile
359070	SHOE COVER	73324300000000097KH	15056 Shoe cover, non-conductive, non-sterile