

Title: Elset / Elset S

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We, Mölnlycke Health Care AB, Gamlestadsvägen 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:	Elset / Elset S
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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: **IV**

Common Specification: **No CS is applicable**

Certificate number: **Not Applicable**

Issued by: **Not Applicable**

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 all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Date: **2020-07-10**

Function: **Regulatory Affairs Director**

Name: **Christina Lewing**

Signature:



Intended Purpose: Type 3A light compression bandage used to provide compression for the leg following vascular surgery and for general surgical and orthopaedic use.

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
3482	Elset 10cm x 6m stretched	733243000000000060JS	59014 Pressure bandage, Hevea-latex, single-use, non-sterile
3489	Elset 10cm x 8m stretched	733243000000000060JS	59014 Pressure bandage, Hevea-latex, single-use, non-sterile
993483	Elset 15cm x 6m stretched	733243000000000060JS	59014 Pressure bandage, Hevea-latex, single-use, non-sterile
993486	Elset S 10cm x 12m stretched	733243000000000060JS	59014 Pressure bandage, Hevea-latex, single-use, non-sterile
993487	Elset S 15cm x 12m stretched	733243000000000060JS	59014 Pressure bandage, Hevea-latex, single-use, non-sterile