



EU Declaration of Conformity according to MDR

Document ID: PD-576925 Rev: 00
Created by: Pam Hague
Approved by: Christina Lewing
Approval date: 2020-07-10

Title: Tubigrip

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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:	Tubigrip
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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
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Common Specification:	No CS is applicable
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Certificate number:	Not Applicable
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Issued by:	Not Applicable
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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:

Title: Tubigrip

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Intended Purpose: Provides firm support for sprains, strains and swelling

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
1434	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1435	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1436	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1437	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1438	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1439	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1440	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1441	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1442	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1443	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1444	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1448	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1449	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
1450	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1451	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1452	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1453	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1510	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1511	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1512	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1513	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1514	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1515	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1520	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1521	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1522	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1523	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1524	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1528	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage



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Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
1545	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1546	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1547	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage
1548	Elasticated tubular bandage	733243000000000063JY	10279 Active-support bandage