



EU Declaration of Conformity according to MDR

Document ID: PD-576925 Rev:01
Created by: Richard Crisp
State: Released
Approved by: Christina Lewing
Release date: 2021-11-02 16:28:30

Title: Tubigrip

Dates and times in Greenwich Mean Time, 24 hours format

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 the 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: MDR Class I ns

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

Id No:

(Notified Body Name)

Note. For non-sterile, non-measuring class I products there is no Notified Body certificate

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

Signed for and on behalf of Mölnlycke Health Care

Place of Issue: Göteborg, Sweden

Date: 2021-11-02

Function:

Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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Generic product information	
Intended Purpose:	Provides firm support for sprains, strains and swelling
Basic UDI-DI:	733243000000000063JY
GMDN Code:	61653 Tubular support bandage, Hevea-latex

Product References Covered by this Declaration:	Product Descriptor:
1434	Elasticated tubular bandage
1435	Elasticated tubular bandage
1436	Elasticated tubular bandage
1437	Elasticated tubular bandage
1438	Elasticated tubular bandage
1439	Elasticated tubular bandage
1440	Elasticated tubular bandage
1441	Elasticated tubular bandage
1442	Elasticated tubular bandage
1443	Elasticated tubular bandage
1444	Elasticated tubular bandage
1448	Elasticated tubular bandage
1449	Elasticated tubular bandage
1450	Elasticated tubular bandage
1451	Elasticated tubular bandage
1452	Elasticated tubular bandage
1453	Elasticated tubular bandage
1510	Elasticated tubular bandage
1511	Elasticated tubular bandage
1512	Elasticated tubular bandage



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1513	Elasticated tubular bandage
1514	Elasticated tubular bandage
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1521	Elasticated tubular bandage
1522	Elasticated tubular bandage
1523	Elasticated tubular bandage
1524	Elasticated tubular bandage
1528	Elasticated tubular bandage
1545	Elasticated tubular bandage
1546	Elasticated tubular bandage
1547	Elasticated tubular bandage
1548	Elasticated tubular bandage