



EU Declaration of Conformity according to MDR

Document ID: **PD-576916 Rev: 00**
Created by: Pam Hague
Approved by: Christina Lewing
Approval date: 2020-07-10

Title: Tubifast

Page 1(4)

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:	Tubifast
------------------------------	-----------------

Product classification: **I**

MDR Classification Rule: **4**

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:

Title: Tubifast
Page 2(4)
Intended Purpose: For Dressing Retention, wet or dry wrapping

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
2434	Elasticated Viscose Tubular Bandage	733243000000000064K2	61652 Tubular support bandage, non-latex, reusable
2436	Elasticated Viscose Tubular Bandage	733243000000000064K2	61652 Tubular support bandage, non-latex, reusable
2438	Elasticated Viscose Tubular Bandage	733243000000000064K2	61652 Tubular support bandage, non-latex, reusable
2440	Elasticated Viscose Tubular Bandage	733243000000000064K2	61652 Tubular support bandage, non-latex, reusable
2444	Elasticated Viscose Tubular Bandage	733243000000000064K2	61652 Tubular support bandage, non-latex, reusable
2446	Elasticated viscose tubular bandage	733243000000000064K2	61652 Tubular support bandage, non-latex, reusable
2447	Elasticated Viscose Tubular Bandage	733243000000000064K2	61652 Tubular support bandage, non-latex, reusable
2448	Elasticated Viscose Tubular Bandage	733243000000000064K2	61652 Tubular support bandage, non-latex, reusable
2479	Elasticated Viscose Tubular Bandage	733243000000000064K2	61652 Tubular support bandage, non-latex, reusable

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
2480	Elasticated Viscose Tubular Bandage	733243000000000064K2	61652 Tubular support bandage, non-latex, reusable
2481	Elasticated Viscose Tubular Bandage	733243000000000064K2	61652 Tubular support bandage, non-latex, reusable
2482	Elasticated Viscose Tubular Bandage	733243000000000064K2	61652 Tubular support bandage, non-latex, reusable
2483	Elasticated Viscose Tubular Bandage	733243000000000064K2	61652 Tubular support bandage, non-latex, reusable
3555	Elasticated Viscose Tubular Bandage	733243000000000064K2	61652 Tubular support bandage, non-latex, reusable
3556	Elasticated Viscose Tubular Bandage	733243000000000064K2	61652 Tubular support bandage, non-latex, reusable
3557	Elasticated Viscose Tubular Bandage	733243000000000064K2	61652 Tubular support bandage, non-latex, reusable
3558	Elasticated Viscose Tubular Bandage	733243000000000064K2	61652 Tubular support bandage, non-latex, reusable
5920	Tubifast gloves	733243000000000064K2	60522 Skin treatment glove, reusable
5921	Tubifast gloves	733243000000000064K2	60522 Skin treatment glove, reusable
5922	Tubifast gloves	733243000000000064K2	60522 Skin treatment glove, reusable
5923	Tubifast gloves	733243000000000064K2	60522 Skin treatment glove, reusable
992007	Tubifast garments, vest 6 - 24 months	733243000000000064K2	60527 Skin treatment upper-body garment

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
992008	Tubifast garments, vest 2 - 5 years	733243000000000064K2	60527 Skin treatment upper-body garment
992009	Tubifast garment, vest 5 - 8 years	733243000000000064K2	60527 Skin treatment upper-body garment
992010	Tubifast garment, vest 8 - 11 years	733243000000000064K2	60527 Skin treatment upper-body garment
992011	Tubifast garment, vest 11 - 14 years	733243000000000064K2	60527 Skin treatment upper-body garment
992012	Tubifast garment, legging 6 - 24 months	733243000000000064K2	60525 Skin treatment lower body garment
992013	Tubifast garment, legging 2 - 5 years	733243000000000064K2	60525 Skin treatment lower body garment
992014	Tubifast garment, legging 5 - 8 years	733243000000000064K2	60525 Skin treatment lower body garment
992015	Tubifast garment, legging 8 - 11 years	733243000000000064K2	60525 Skin treatment lower body garment
992016	Tubifast garment, legging 11 - 14 years	733243000000000064K2	60525 Skin treatment lower body garment
992017	Tubifast garment, sock one size	733243000000000064K2	60526 Skin treatment sock
992485	Elasticated Viscose Tubular Bandage	733243000000000064K2	61652 Tubular support bandage, non-latex, reusable
992486	Elasticated Viscose Tubular Bandage	733243000000000064K2	61652 Tubular support bandage, non-latex, reusable
992487	Elasticated Viscose Tubular Bandage.	733243000000000064K2	61652 Tubular support bandage, non-latex, reusable