

Title: Tubifast

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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:	Tubifast
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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 applied harmonised standards.

Signed for and on behalf of Mölnlycke Health Care AB

Place of Issue: Göteborg, Sweden

Date: **2021-03-25**

Function: **Regulatory Affairs Director**

Name: **Christina Lewing**

Signature:





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	73324300000000064K2	61652 Tubular support bandage, non-latex, reusable
2436	Elasticated Viscose Tubular Bandage	73324300000000064K2	61652 Tubular support bandage, non-latex, reusable
2438	Elasticated Viscose Tubular Bandage	73324300000000064K2	61652 Tubular support bandage, non-latex, reusable
2440	Elasticated Viscose Tubular Bandage	73324300000000064K2	61652 Tubular support bandage, non-latex, reusable
2444	Elasticated Viscose Tubular Bandage	73324300000000064K2	61652 Tubular support bandage, non-latex, reusable
2446	Elasticated viscose tubular bandage	73324300000000064K2	61652 Tubular support bandage, non-latex, reusable
2447	Elasticated Viscose Tubular Bandage	73324300000000064K2	61652 Tubular support bandage, non-latex, reusable
2448	Elasticated Viscose Tubular Bandage	73324300000000064K2	61652 Tubular support bandage, non-latex, reusable
2449	Elasticated Viscose Tubular Bandage	73324300000000064K2	61652 Tubular support bandage, non-latex, reusable



**EU Declaration of Conformity
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Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
2479	Elasticated Viscose Tubular Bandage	73324300000000064K2	61652 Tubular support bandage, non-latex, reusable
2480	Elasticated Viscose Tubular Bandage	73324300000000064K2	61652 Tubular support bandage, non-latex, reusable
2481	Elasticated Viscose Tubular Bandage	73324300000000064K2	61652 Tubular support bandage, non-latex, reusable
2482	Elasticated Viscose Tubular Bandage	73324300000000064K2	61652 Tubular support bandage, non-latex, reusable
2483	Elasticated Viscose Tubular Bandage	73324300000000064K2	61652 Tubular support bandage, non-latex, reusable
3555	Elasticated Viscose Tubular Bandage	73324300000000064K2	61652 Tubular support bandage, non-latex, reusable
3556	Elasticated Viscose Tubular Bandage	73324300000000064K2	61652 Tubular support bandage, non-latex, reusable
3557	Elasticated Viscose Tubular Bandage	73324300000000064K2	61652 Tubular support bandage, non-latex, reusable
3558	Elasticated Viscose Tubular Bandage	73324300000000064K2	61652 Tubular support bandage, non-latex, reusable
5920	Tubifast gloves	73324300000000064K2	60522 Skin treatment glove, reusable
5921	Tubifast gloves	73324300000000064K2	60522 Skin treatment glove, reusable
5922	Tubifast gloves	73324300000000064K2	60522 Skin treatment glove, reusable



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Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
5923	Tubifast gloves	73324300000000064K2	60522 Skin treatment glove, reusable
992007	Tubifast garments, vest 6 - 24 months	73324300000000064K2	60527 Skin treatment upper-body garment
992008	Tubifast garments, vest 2 - 5 years	73324300000000064K2	60527 Skin treatment upper-body garment
992009	Tubifast garment, vest 5 - 8 years	73324300000000064K2	60527 Skin treatment upper-body garment
992010	Tubifast garment, vest 8 - 11 years	73324300000000064K2	60527 Skin treatment upper-body garment
992011	Tubifast garment, vest 11 - 14 years	73324300000000064K2	60527 Skin treatment upper-body garment
992012	Tubifast garment, legging 6 - 24 months	73324300000000064K2	60525 Skin treatment lower body garment
992013	Tubifast garment, legging 2 - 5 years	73324300000000064K2	60525 Skin treatment lower body garment
992014	Tubifast garment, legging 5 - 8 years	73324300000000064K2	60525 Skin treatment lower body garment
992015	Tubifast garment, legging 8 - 11 years	73324300000000064K2	60525 Skin treatment lower body garment
992016	Tubifast garment, legging 11 - 14 years	73324300000000064K2	60525 Skin treatment lower body garment
992017	Tubifast garment, sock one size	73324300000000064K2	60526 Skin treatment sock
992485	Elasticated Viscose Tubular Bandage	73324300000000064K2	61652 Tubular support bandage, non-latex, reusable
992486	Elasticated Viscose Tubular Bandage	73324300000000064K2	61652 Tubular support bandage, non-latex, reusable



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Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
992487	Elasticated Viscose Tubular Bandage.	73324300000000064K2	61652 Tubular support bandage, non-latex, reusable

Revision history	
Revision	Comment
01	addition of new code 2449 Tubifast Blue 10m x 10m to the DoC