Declaration of Conformity EU

Document ID:	**PD-434108 Rev: 02**
Created by:	Anu-Maria Hokkanen
Approved by:	Karin Darle Olsson
Approval date:	2021-01-15

Title: Lyofoam Max T

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 Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade name/ Product name:	**Lyofoam Max T**

Product classification:	**IS**
Sterility Status:	**Sterile**
Measuring function:	**No**

This declaration is supported by a conformity assessment procedure in accordance with

Annex/es:	**V, VII**

Certificate number:	**CE 01966**
Issued by:	**BSI (2797)**

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 M ö lnlycke Health Care

Date:	**2021-01-15**	Function:	**Regulatory Affairs Manager Compliance**
Name:	**Karin Darle Olsson**	Signature:	

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Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	GMDN Code:
603207	Absorbent tracheostomy dressing	15624 Tracheostomy tube dressing, sterile