



**EU Declaration of Conformity  
according to MDR**

**Document ID:** PD-596212 **Rev:**01  
**Created by:** Gayle Wood  
**State:** Released  
**Approved by:** Christina Lewing  
**Release date:** 2021-12-13 17:22:32

**Title:** Bulk non-sterile, tube holders

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:	Bulk non-sterile, patient drapes
----------------------------	----------------------------------

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:
	<i>(Notified Body Name)</i>	
<i>Note. For non-sterile, non-measuring class I products there is no Notified Body certificate</i>		

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: 2021-12-13                      Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



**EU Declaration of Conformity  
according to MDR**

**Document ID:** PD-596212 Rev:01  
**Created by:** Gayle Wood  
**State:** Released  
**Approved by:** Christina Lewing  
**Release date:** 2021-12-13 17:22:32

**Title:** Bulk non-sterile, tube holders

Dates and times in Greenwich Mean Time, 24 hours format

Generic product information	
<b>Intended Purpose:</b>	The tube holder is attached to other draped areas and used to attach and manage tubes and cables during a surgical procedure. The tube holder is provided non-sterile for final packaging and sterilisation prior to use.
<b>Basic UDI-DI:</b>	733243000000000225K2
<b>GMDN Code:</b>	62137 Medical/surgical interventional tube/cable securement clip, single-use

Product References Covered by this Declaration:	Product Descriptor:
824098	TUBE HOLDER
904762	TUBE HOLDER