EU Declaration of Conformity according to MDR

Title: Sterile op-tape

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden, SRN SE-MF-000014042, 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:	Sterile op-tape

Product Classification:	MDR Class IS
MDR Classification Rule:	1
Sterility:	Sterile
Measuring Function:	No

This declaration is supported by a conformity assessment procedure in accordance with Annex/es: IX
Common Specification: No CS is applicable

Certificate number:	MDR 722028		
Issued by:	BSi	Id No:	2797
	(Notified Body Name)		

NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.

Mölnlycke Health Care AB issues this declaration in recognition of applied harmonized standards.

Signed for and on behalf of Mölnlycke Health Care AB

Place of Issue: Göteborg, Sweden

Date: 2024-01-23 Function: Global Regulatory Affairs Director

Name: Christina Lewing Signature:



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Generic product information	
Intended Purpose:	The OP-tape is intended to be used to attach drapes to the patient or other drapes to enable a sterile field.
Basic UDI-DI:	733243000000000224JY
GMDN Code:	58986 Multi-purpose surgical skin adhesive tape
EMDN Code:	T020199 SURGICAL DRAPES - OTHER

Product References Covered by this Declaration:	Product	Product Descriptor:
381035	OP-tape 9x49cm	OP-TAPE
381045	OP-tape 9x49cm, 2-pcs	OP-TAPE