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:	Universal HP Surgical Gowns

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)		

Note. For non-sterile, non-measuring class I products there is no Notified Body certificate

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: 2021-07-12 Function: Global Regulatory Affairs Director

Name: Christina Lewing Signature:



Generic product information	
Intended Purpose:	Surgical Gowns are single use, fluid repellent garments intended to be used as sterile by operating room personnel during surgical procedures to protect both the patient and the operating room personnel (users) from the transfer of micro-organisms, body fluids and particulate material.
Basic UDI-DI:	733243000000000192KC
GMDN Code:	35091 Operating room gown, single-use

Product References Covered by this Declaration:	**Product Descriptor:**
93000720	SURGICAL GOWN
93000721	SURGICAL GOWN
93000722	SURGICAL GOWN
93000723	SURGICAL GOWN
93000724	SURGICAL GOWN
93000725	SURGICAL GOWN