We, Mölnlycke Health Care, 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 Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable:	**Not applicable**

Trade name/ Product name:	**Mepore IV**

Product classification:	**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 (2797)**

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:	**2021-05-05**	Function:	**Regulatory Affairs Director**
Name:	**Christina Lewing**	Signature:	

Intended Purpose: Mepore IV is intended for fixation of intravascular devices such as IV catheters or other intravascular catheters

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
274000	Transparent, adhesive IV film dressing	733243000000000007JN	58301 Synthetic polymer semi-permeable film dressing, adhesive, sterile
274200	Transparent, adhesive IV film dressing	733243000000000007JN	58301 Synthetic polymer semi-permeable film dressing, adhesive, sterile
274400	Transparent, adhesive IV film dressing	733243000000000007JN	58301 Synthetic polymer semi-permeable film dressing, adhesive, sterile