Declaration of Conformity

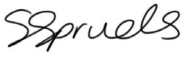
for Insil Silicone Tape

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices as transposed into European national law by the member states.

This declaration is issued under the sole responsibility of Insight Medical Products Ltd. The products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Insil Silicone Tape
Legal Manufacturer: (Name on Label)	Insight Medical Products Ltd. Unit 3, Priory Industrial Estate, Tetbury, Gloucestershire. GL8 8HZ. United Kingdom
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Manufacturers SRN:	SRN No: GB-MF-000004395
Intended Use:	Insil Silicone Tape prevents pressure damage and sores to the patient during fixation of most medical devices. Insil prevents stripping of the epidermal skin layer with the silicone adhesive properties. Insil Silicone Tape is only intended to be used for fixating devices and tubes, or prevention of sores and is not for use on open wounds or scars. Do not use on broken skin or if allergic to silicone.
MDR 2017/745 Risk Classification:	Class I (non-invasive) Annex VIII, Rule 1
Notified Body:	Not Applicable for Class I
EC Certificate:	Not applicable for Class I (Non-Sterile)
Quality Management Certificate:	GB07/72387
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
Conformity Assessment Route:	Article 52, section 7 of MDR 2017/745 Technical Documentation: Annex II and Annex III of MDR 2017/745

Name Stacey Spruels **Position** Quality and Regulatory Manager

Signed  **Date** 26/05/2021

Town/Country of signing: Tetbury, Gloucestershire. United Kingdom.

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
(EU) MDR 2017/745	Regulation (EU) 2017/745 concerning medical devices
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
BS EN 15223-1:2016	Medical Devices –Symbols to be used with Medical Devices

Appendix II – Product Listing/Schedule

Product Ref	Description	GMDN Code	Basic-UDI (B-UDI)
INSIL/200	Insil Silicone Tape -2cm x 3m	58749	506041364TF011VX
INSIL/400	Insil Silicone Tape -4cm x 1.5m	58749	506041364TF011VX