
EC Declaration of Conformity

Manufacturers Name: Adhezion Biomedical, LLC.

Manufacturers Address: 506 Pine Mountain Road Hudson NC 28638
United States of America

SRN (Single Registration Number): **3029780**

Authorized Representative Name (if applicable): Emergo Europe

Authorized Representative Address (if applicable): Prinsessegracht 20 2514 AP The Hague The Netherlands

Basic UDI-DI: Please see table at end of document.

Name of the Device (s): SurgiSeal, SurgiSeal Stylus (0.50ml), SurgiSeal Twist

Product code: SS-035T, SS-050S, ST-050S

Classification: Class IIa – Annex IX, Rule 4

Notified Body name: INTERTEK SEMKO AB

Notified Body Address: Torshamnsgatan 43 Box 1103 SE-164 22 KISTA Sweden

Notified Body Identification number: 0413

Conformity assessment route: Adhezion Biomedical, LLC. uses the following procedures for the CE-labeling of their products according to Regulation MDR 2017/745:

Class IIa: EC conformity declaration according to Medical Device Directive 93/42/EEC- Annex V
Certificate #: 4130110990
Issued: 23 February 2021
Expiry date: 26 May 2024

QMS Certificate: Issued by Intertek Testing Services NA, Inc
Certificate #: 0083419
Issued: 2018-11-08

This declaration of conformity is issued under the sole responsibility of Adhezion Biomedical, LLC. We hereby declare that the medical device(s) specified above, SurgiSeal Topical Skin Adhesives, meet the applicable requirements of the Medical Devices Act (1993:584) and the Medical Products Agency Regulation LVFS 2003:11 for medical devices transposing European Medical Devices Directive 93/42/EEC. This declaration is supported by the Quality System conformance to ISO 13485. All supporting documentation is retained at the premises of the manufacturer.

Signature:

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Janet L. Huntsinger
Director, QA/RA

Date:

02/15/2022

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Applicable Standards

EN ISO 13485: 2016 - Medical Devices - Quality Management Systems

EN ISO 14971- Medical Devices - Application of Risk

EN ISO 10993 - Biological Evaluation of Medical Devices

ISO 639-1- Codes for the representation of names of languages

ISO 15223-1 - Medical Devices - Symbols to be used with medical device labels, labelling and information supplied

EN980 - Symbols for use in the labelling of medical devices

EN1041- Information supplied by the manufacturer of medical devices EN/ISO 11607 - Packaging for terminally sterilized medical devices

EN ISO 11135 - Validation and Routine Control of Ethylene Oxide Sterilization

EN 556-1- Sterilization of Medical Devices for Terminally Sterilized Product Labeled "Sterile" EN ISO 11737 - Sterilization of Medical Devices - Microbiological Methods

AAMI/ANSI/ISO 11137 Sterilization of Health Care Products - Radiation

EN ISO 11138 - Sterilization of Health Care Products - Biological Indicators

EN ISO 10993-7 - Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals

Product UDIs**SurgiSeal Single Unit**

Product Name	SKU#	UDI Number
SurgiSeal Stylus	SS-050S	0089137500203
SurgiSeal Teardrop	SS-035T	0089137500200
SurgiSeal Twist	ST-050S	0089137500208

SurgiSeal UNIT BOX (12 ea)

Product Name	SKU#	UDI Number
SurgiSeal Stylus	SS-050S	1089137500203
SurgiSeal Teardrop	SS-035T	1089137500200
SurgiSeal Twist	ST-050S	1089137500200