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 Hauge The Netherlands
Basic UDI-DI:	Please see table at end of document.
Name of the Device (s):	SecurePortIV™ Catheter Securement Adhesive
Product code:	SP-015V, SP-015V50
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 Certifiacte #: 4130110990 Issued: 23 February 2021 Expiry date: 26 May 2024 QMS Cerificate: Issued by Intertek Testing Services NA, Inc Certifiacte #: 0083419 Issued: 2018-11-08 Expiry date: 2022-06-03

This declaration of conformity is issued under the sole responsibility of Adhezion Biomedical, LLC. We hereby declare that the medical device(s) specified above, SecurePortIV™ Catheter Securement 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: Janet L. Huntsinger

Date: 28-MAR-2022

Janet L. Huntsinger
Director, QA/RA

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

SecurePortIV ™ Single Unit

Product Name	SKU#	UDI Number
SecurePortIV ™	SP-015V	00891375002092

SecurePortIV ™ UNIT BOX (50 ea)

Product Name	SKU#	UDI Number
SecurePortIV ™	SP-015V50	10891375002099