EC CERTIFICATION

PRODUCTION QUALITY ASSURANCE

Directive 93/42/EEC on Medical Devices, Annex V

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Adhezion Biomedical, LLC

Main Site: 506 Pine Mountain Road, Hudson, North Carolina, 28638, United States

Product Category:

- Cyanoacrylate based adhesive, Class IIa, for medical uses,

For further identification of the products covered, see the MDD product list/product schedule.

Certificate Number:
4130110990

Initial Certification Date:
23 February 2021

Certificate Valid from:
23 February 2021

Certificate Expiry Date:
26 May 2024

SWEDAC ACKREDITERING
Accred. no. 1003
Certification of Management Systems
ISO/IEC 17021-1

Mikael Hagelin
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

23 February 2021
Signed Date

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

MDD – Product List

T103-3-SE-MDD

Products included in the certificate no: 4130110990
Issued to: **Adhezion Biomedical LLC**
506 Pine Mountain Road,
Hudson, North Carolina, 28638,
United States

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Cyanoacrylate Tissue Adhesive					
	FS-250D FloraSeal	IIa	Yes	n/a	23 February 2021
	SS-035T SurgiSeal Teardrop	IIa	Yes	n/a	23 February 2021
	SS-050S Surgiseal Stylus	IIa	Yes	n/a	23 February 2021
	SS-050S Surgiseal Twist	IIa	Yes	n/a	23 February 2021
	SP-015V50 SecurePortIV	IIa	Yes	n/a	23 February 2021

Date of Issue: 23 February 2021

Intertek Semko AB
Notified Body MDD

Mikael Hagelin
Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

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Registered in Sweden: No SE556024059901, Registered office: As address

MDD – Decision Report

Certificate No: 4130110990
Date: 23 February 2021
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

Adhezion Biomedical, LLC
Attn: Janet L Huntsinger
506 Pine Mountain Road,
Hudson, North Carolina, 28638,
United States

Purpose	Assessment to issue a new certificate for new client according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex V.
Activity	Certification audit was performed 28 October 2020 in Hudson by Anne Hickman. The technical file was reviewed 22 February 2021 by Tiina Riihimäki.at Intertek's office.
Scope of assessment	Cyanoacrylate based adhesive, Class IIa, for medical uses
Result	0 non conformities were noted during the audit.
Certificate Valid from	23 February 2021
Conclusions/Decisions	Referring to the above a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex V will be issued. The Certificate is valid for products specified in the "MDD – Product List".
Follow-up assessments	Follow-up assessments are going to be performed once a year.
Appeals	Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.
Others	Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Semko has the right to review this documentation.

Intertek Semko AB
Notified Body MDD

Mikael Hagelin
Certification Authority MDD