Declaration of Conformity

In accordance with Medical Devices Directive 93/42/EEC

We herewith declare that the under-mentioned device, in view of its design and type of construction, meets the essential health and safety requirements of the above EC Directive 93/42/EEC as amended by Directive 2007/47/EC. If the device is modified without the agreement of the under-designed, this declaration becomes invalid.

Manufacturer: Suzhou Silvan Medical Device Co., Ltd.

Address: First Floor, Building No.7 of Lianfa Industrial Park, 158 Hongye Road, Suzhou Industrial Park, Jiangsu Province, China

European Representative: Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Product: Vascular Closure System

Brand name: Clothoid

Specification: 6F

REF Code: FS910001

Classification: Class III

Related Directives and Annex: 93/42/EEC Medical Devices Directive – Annex II (Excluding Section 4)

GMDN Code: 52747

Digitally signed by Ostapciuc Alexandr
Date: 2023.10.12 11:25:28 EEST
Reason: MoldSign Signature
Location: Moldova

The product identified above complies with the essential requirements of the above EC Directives by meeting the following standards:

Appendix I: Applied standard list

This Declaration of Conformity is based on the EC Directives 93/42/EEC, Annex II (exclude 4) under the supervision of Notified body, UDEM (NB No. 2292).

Notified body:

UDEM ULUSLARARASI BELGELENDİRME DENETİM EĞİTİM MERKEZİ SAN. VE TİC. LTD. ŞTİ.

EC Certificate No.: M.2021.106.14582
Issue date: 19/05/2021
Valid until: 27/05/2024

Director of RA/QA on behalf of Suzhou Silvan Medical Device Co., Ltd.
Place: First Floor, Building No.7 of Lianfa Industrial Park, 158 Hongye Road, Suzhou Industrial Park, Jiangsu Province, China

Name and signature or equivalent marking of authorized person

Yachuan Yu

Signature:

Date: 2021.05.03

Appendix I: Applied standard list

NO	Standard reference	Standard Title
1.	EN ISO 13485:2016	Medical devices—Quality management systems—Requirements for regulatory purposes
2.	MDD 93/42/EEC	Council Directive concerning medical devices
3.	EN ISO 14971:2019	Medical devices-Application of risk management to medical devices
4.	EN 1041:2008/A1:2013	Information supplied by the manufacturer of medical devices
5.	EN ISO11607-1:2020	Packaging for terminally sterilized medical devices-- Part 1: Requirements for materials, sterile barrier systems and packaging systems
6.	EN ISO11607-2:2020	Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes
7.	EN ISO 10993-1:2020	Biological evaluation of medical devices — Part 1: Evaluation and testing
8.	EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
9.	EN ISO 10993-4:2009	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
10.	EN ISO 10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
11.	EN ISO 10993-6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation

12.	EN ISO 10993-7:2008	Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals

13.	EN ISO 10993-10:2013	Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity
14.	EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
15.	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements
16.	EN ISO 11135-2014 /A1:2019	Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
17.	EN556-1:2001	Sterilization of medical devices--- Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
18.	IEC 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
19.	EN ISO 14630:2012	Non-active surgical implants. General requirements
20.	MDCG 2020-13Word version	Clinical evaluation assessment report template
21.	MDCG 2020-10/2 MDCG 2020-10/1	Guidance on safety reporting in clinical investigations Appendix: Clinical investigation summary safety report form
22.	MDCG 2020-8	Guidance on PMCF evaluation report template

23.	MDCG 2020-7	Guidance on PMCF plan template
24.	MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices
25.	MDCG 2020-5	Guidance on clinical evaluation – Equivalence
26.	MDCG 2019-9	Summary of safety and clinical performance
27.	MDCG 2020-15	MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States
28.	MDCG 2019-5	Registration of legacy devices in EUDAMED
29.	MDCG 2019-4	Timelines for registration of device data elements in EUDAMED
30.	MDCG 2020-18	MDCG Position Paper on UDI assignment for Spectacle lenses & Ready readers
31.	MDCG 2019-1	MDCG guiding principles for issuing entities rules on basic UDI-DI
32.	MDCG 2018-7	Provisional considerations regarding language issues associated with the UDI database
33.	MDCG 2018-6	Clarifications of UDI related responsibilities in relation to article 16
34.	MDCG 2018-5	UDI assignment to medical device software
35.	MDCG 2018-4	Definitions/descriptions and formats of the UDI core elements for systems or procedure packs
36.	MDCG 2018-3 Rev.1	Guidance on UDI for systems and procedure packs
37.	MDCG 2018-2	Future EU medical device nomenclature - Description of requirements
38.	MDCG 2018-1 v3	Guidance on basic UDI-DI and changes to UDI-DI
39.	MDCG 2019-13	Guidance on sampling of devices for the assessment of the technical documentation
40.	MDCG 2019-10 rev.1	Application of transitional provisions concerning validity of certificates issued in accordance to the directives
41	MDCG 2021-25	Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC

42.	NBOG BPG 2014-3	Guidance for manufacturers and Notified Bodies on reporting of Design Changes and Changes of the Quality System
43.	NBOG BPG 2009-2	Role of Notified Bodies in the Medical Device Vigilance System
44.	NBOG BPG 2009-1	Guidance on Design-Dossier Examination and Report Content
45.	NBOG BPG 2006-1	Change of Notified Body
46.	NBOG BPG 2014-3	Guidance for manufacturers and Notified Bodies on reporting of Design Changes and Changes of the Quality System
47.	NBOG CL 2010-1	Checklist for audit of Notified Body's review of Clinical Data/Clinical Evaluation
48.	NBOG BPG 2014-3	Guidance for manufacturers and Notified Bodies on reporting of Design Changes and Changes of the Quality System

MEDICAL DEVICE CONTENT DECLARATION

We declare that our products (products which including models Clothoid 6F and GMDN code) does not include:

- Drug and Medical Device Combination, according to as per article 1 of 2001/83/EEC regulation
- devices manufactured utilising derivatives of tissues or cells of human origin referred to in section 7.4 of annex I of Directive 93/42/EEC as amended by Directive 2007/47/EC of the European Parliament and of the council.
- Tissues of animal origin referred to in directive 722/2012 of the European parliament and of the council

Suzhou Silvan Medical Device Co., Ltd.

General Manager: Zhang Lei

Date: 2019.10.03