

Name: EU Declaration of Conformity		Version: Rev.1
No.: VC/CE-03-01	Validated Date: 2026-08-04	Page 1 of 1
Compiled by: Lu Ying	Audited by: Zhang Song	Approved by: Xiang Liang

EU Declaration of Conformity

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Name: Suzhou Vicon Industrial Co., Ltd.

Manufacturer: Address: NO.11, Shitian Road, Yangchenghu Town, Xiangcheng District, 215122 Suzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

SRN: CN-MF-000028246

European Name: SUNGO Europe B.V.

Representative: Address: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands

SRN: NL-AR-000000247

MDR Certificate No. G21 092387 0006 Rev.01

Certificate is valid until 2029-05-21

Notified Body TÜV SÜD Product Service GmbH, Ridlerstraße. 65, 80339 Munich, Germany.

Identification Number: 0123

Product Name: Sterile Non-adherent Dressing

Trade Name: N.A.

REF: NR20-VSBV-0-01

Product Sizes: 60*80cm

Intended purpose Sterile Non-adherent Dressing is applicable for clearing trauma, absorbing blood and isolating wound in surgery.

Basic UDI-DI: 697566225NONADHERENTSM

EMDN Code: M04

Classification Acc. to MDR Annex VIII: Class Is, Rule 4

Applied Common Specification/ standard:

EN ISO 13485:2016	EN ISO 14971:2019/A11:2021	EN ISO 10993-1:2020
EN ISO 10993-5:2009	EN ISO 10993-10:2023	EN ISO 15223-1:2021
EN ISO 10993-23:2021	EN ISO 20417: 2021	EN 62366-1: 2015+A1:2020
EN ISO 11607-1:2020	EN ISO 11607-2:2020	EN ISO 11137-1:2015/A2:2019

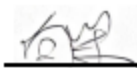
Conformity Assessment Procedure: MDR Annex XI, Part A

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR), any other relevant Union legislation that provides for the issuing of an EU declaration of conformity, any CS used and in relation to which conformity is declared and other relevant regulations. All supporting documentations are retained under the premises of the manufacturer.

Place of Issue: Suzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Date of Issue: 2026.08.04

valid until: 2029-05-21

Signature: 

Name: Mr. Xiang Liang

Position: PRRC