



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

SUNGO Europe B.V.  
Fascinatio Boulevard 522, Unit 1.7,  
2909VA Capelle aan den IJssel, The  
Netherlands  
SRN: NL-AR-00000247

## Conformity Assessment

### Conformity Assessment Procedure

#### Applicable Standards

EN ISO14971:2019  
EN ISO15223-1:2016  
ISO10993-1:2018  
EN ISO10993-5:2009  
EN ISO10993-10:2010  
EN 1041:2008+A1:2013  
EN 62366-1:2015

### Remark

The declaration of conformity is valid in connection with the release technical document [CE/MDR-SM03](#).

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

## Manufacturer

Name: Wenzhou Scico Medical Corporation Co.,Ltd.  
Address: 43 Building, Xinya Industrial Park,  
Longgang Wenzhou, Zhejiang Province; China,  
325802  
SRN: CN-MF-000015370

## Product Information

Name: Elastic Adhesive Bandage  
Model: EAB  
GMDN: 34864  
Basic UDI-DI: 697345106EABNX  
Classification: Class I

## Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:

Chen Jiasen

Position: GM

Date: 2023.10.08

Place: Wenzhou China

