



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

SUNGO Europe B.V.  
Olympisch Stadion 24, 1076DE  
Amsterdam, Netherlands  
SRN: NL-AR-000000247

## Conformity Assessment

Conformity Assessment Procedure  
Annex II+III of Regulation (EU) 2017/745

### Applicable Standards

- EN ISO 14971: 2019
- EN ISO 15223-1: 2016
- EN 1041:2008+A1:2013
- ISO 10993-1: 2018
- EN ISO 10993-5: 2009
- EN ISO 10993-10: 2013
- EN ISO 10993-11:2017
- DIN 58953-6:2016
- EN868-1,EN868-2,EN868-5

### Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-CD-01.

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: ANQING CLEAN DENTAL INSTRUMENT TECHNOLOGY CO., LTD

Address: Floor 2, D4-A, Jiabao Industrial Park, Yangtze River Bridge, Economic Development Zone, 246000, Anqing City, Anhui Province, China

## Product Information

Name: Sterilization pouch/Reel

Model: SEE ANNEX

GMDN: 13735

Basic UDI-DI: 697543453P001H7

Classification: According to Rule 1, Annex VIII Regulation (EU) 2017/745

## 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: Alex Wang Date: 2022.7.8

Position:GM

Place: Anhui/China



## Annex

Product Name	Model	GMDN	Basic UDI-DI
Sterilization pouch/Reel	57mm*90mm, 57mm*100mm, 57mm*130mm, 70mm*260mm, 90mm*135mm, 90mm*165mm, 90mm*170mm, 90mm*260mm, 110mm*280mm, 135mm*260mm, 135mm*280mm, 140mm*280mm, 190mm*360mm, 250mm*370mm, 50mm*200m, 55mm*200m, 75mm*200m, 100mm*200m, 150mm*200m, 200mm*200m, 250mm*200m, 300mm*200m, 350mm*200m, 400mm*200m, 75mm*100m, 100mm*100m, 150mm*100m, 200mm*100m, 250mm*100m, 300mm*100m, 400mm*100m, 90mm*50mm*150mm, 90mm*50mm*250mm, 110mm*30mm*190mm, 110mm*45mm*190mm, 140mm*75mm*250mm, 140mm*50mm*330mm, 180mm*95mm*385mm, 190mm*65mm*330mm	13735	697543453P001H7

人有限公司  
 ANQING CLEAN DENTAL INSTRUMENT TECHNOLOGY CO., LTD

Signature: *Alex Wu*

Date:

Position: GM

Place: Anhui/China

安庆市克林登特牙科用品科技有限公司  
 ANQING CLEAN DENTAL INSTRUMENT TECHNOLOGY CO., LTD