

# 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-000000247

## Conformity Assessment

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

**Applicable Standards**  
EN ISO 14971: 2019  
EN ISO 15223-1: 2021  
EN ISO 20417:2021  
EN ISO 10993-1: 2020  
EN ISO 10993-5: 2009  
EN ISO 10993-10: 2013  
EN 62366-1: 2015

## Remark

*The declaration of conformity is valid in connection with the release technical document CEMDR-XH09-01.*

*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:** ZHANGJIAGANG XIEHE MEDICAL APPARATUS AND INSTRUMENTS CO.,LTD.  
**Address:** No.7th, Middle Xinzha Road, Zhashang Industrial Zone, Yangshe Town, Zhangjiagang City, Jiangsu 215600, China  
SRN:CN-MF-000008449

## Product Information

**Name:** Emergency Scissor  
**Model:** XH-21 XH-22  
**GMDN:** 13481  
**Basic UDI-DI:** 6974580870004DU  
**Classification:**Class I, 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: 

Date: 

Position: G.M.

Place: 

