

# 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  
CE/MDR-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: Zhangjiagang

