

# EC Declaration of Conformity

*Manufacturer:*

*EC Representative:*

**Anping Guardian Medical Equipment Co., Ltd.**

500 meters, Nan Sucun, Anping County,  
Hengshui City, Hebei Province, 053600, China  
SRN: CN-MF-000015025

**MedNet EC-REP GmbH**

Borkstrasse 10, 48163 Münster, Germany  
SRN: DE-AR-000000002

Declare under our sole responsibility that the CE Marked medical devices:

Product and Trade Name: Trauma Shear

Product Code: AZ-EMT, AZ-EMT01, AZ-EMT02, AZ-EMT03, AZ-EMT03, AZ-EMT04, AZ-EMT05,  
AZ-EMT06, AZ-EMT06, AZ-EMT07, AZ-EMT08, AZ-TR01, AZ-TR02, AZ-TR03

Basic UDI-DI: 697310523KITNY

Classification (MDR EU 2017/745 Annex VIII, Chapter III, 4.1): Class I, Rule 1

Conformity Assessment Route: Annex II and Annex III

We, the manufacturer, herewith declare under our sole responsibility that the above devices are in conformity with the Medical Device Regulation / MDR (EU) 2017/745 and other relevant union legislation.

Applied Standards:

MDR (EU) 2017/745, EN ISO13485: 2016, EN ISO14971: 2019, EN 1041: 2008+A1:2013, EN ISO15223-1: 2016, IEC 62366:2007, MEDDEV 2.7/1 rev 4, MEDDEV 2.12/1 rev 8.

Place and Date: Hengshui City, Sept. 16, 2022

Name: LIN YONG 

Function: General Manager

Signature: 