

Declaration of Conformity

MANUFACTURER
(name and address): Anping Guardian Medical Equipment Co., Ltd
500 meters west of Nan Su Village, Anping Country, Hengshui
City, 053600, Hebei, P.R. China.
SRN: CN-MF-000015025

AUTHORIZED
REPRESENTATIVE
(name and address): MedNet EC-REP GmbH
Borkstrasse 10, 48163 Münster, Germany
SRN: DE-AR-000000002

PRODUCTS:

Product Name	Product model	Basic UDI-DI	EMDN Code	Classification
Decompression Needle	AZ-DN-01	697310523Needle018E	A019009	Class IIa; Annex VIII, rule 7
	AZ-DN-02	697310523Needle028G		

Intended purpose of device:

The Decompression Needle is a medical device designed for emergency situations, specifically for the treatment of casualties presenting with signs and symptoms indicative of pneumothorax. It effectively expels air from the Pleural cavity, thereby alleviating dyspnea caused by tension pneumothorax.

Annex IX of Regulation (EU) 2017/745

We herewith declare under our sole responsibility that the above-mentioned products meet the applicable provisions of the Regulation (EU) 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer.

STANDARDS
APPLIED: EN ISO 13485:2016, EN ISO 15223-1:2021, EN ISO 20417:2021,
EN ISO 14971:2019+A11:2021, ISO/TR 24971:2020,
EN 62366-1:2015+AMD1:2020, IEC/TR 62366-2:2016,
EN ISO 9626:2016, EN ISO 8536-4:2020,
EN ISO 10993-1:2020, EN ISO 10993-4:2017,
EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO 10993-23:2021,
EN ISO 11737-1:2018/A1:2021, EN ISO 11607-1 2020,
EN ISO 11607-2 2020, ASTM D4169-22.

NOTIFIED BODY: TÜV Rheinland LGA Products GmbH.
Tillystraße 2, 90431, Nürnberg, Germany
NB Identification number: 0197

EU CERTIFICATE: HZ 2594005-1

QMS Certificate
Registration No.: SX 2594005-1

START OF CE MARKING:

Product Name	Models	Specifications	UDI-DI	Date of First CE Marking
Decompression Needle	AZ-DN-01	14gauge×3.25in	6973105232284	Not yet
	AZ-DN-02	10gauge×3.75in	6973105232307	

Place, Date of issue: HengShui City, 2025-10-21

SIGNATURE: *Feng Yanli*

Feng Yanli
General Manager
For and on behalf of Anping
Guardian Medical
Equipment Co., Ltd.

Zhang Yanfeng

Zhang Yanfeng
Person responsible for regulatory
compliance (PRRC)
For and on behalf of Anping Guardian
Medical Equipment Co., Ltd.