

Declaration of Conformity

Manufacturer:

EC Representative:

CH 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

MedNet SWISS GmbH

D4 Platz 4 ,6039 Root

D4,Switzerland

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

Product and Trade Name: Gauze, Tape

Product Code: see attachment

UDI-DI: see attachment

Basic UDI-DI: see attachment

EMDN Code:see attachment

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

Conformity Assessment Route: Annex II and Annex III

Applied Standards:

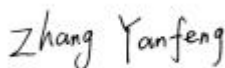
EN ISO13485:2016, EN ISO 14971:2012, EN 1041:2008, EN ISO 14155:2011

ISO 15223-1:2016, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010

A statement that the device that is covered by the present declaration is in conformity with the Medical Device Regulation / MDR(EU) 2017/745 and other relevant union legislation.

Place and Date: Hengshui City, Oct.8th, 2024

Name: Zhang Yanfeng



Function: General Manager

Signature:

安平县嘉德医疗器械有限公司
ANPING GUARDIAN MEDICAL EQUIPMENT CO., LTD

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AP-CE -04-01, A2

Attachment

Product Name	Product Code	UDI-DI	Basic UDI-DI	EMDN Code
Gauze	AZ-GUA	6973105230273	697310523gauze6w	M020102
Tape	AZ-TA	6973105230280	697310523TapeSN	H9002