

	Anji Anshen Surgical Dressings Co., Ltd.	Documentation No.: AS/CE-01-01
	EU Declaration of Conformity	Rev.: A/1
		Effective Date: 2024.08.14

EU Declaration of Conformity

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Name: Anji Anshen Surgical Dressings Co., Ltd.
 Manufacturer: Address: Tangpu Industrial Park, 313300, Huzhou City, Zhejiang Province, China.
 SRN: CN-MF-000013693
 European Name: MedPath GmbH
 Representative: Address: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
 SRN: ES-AR-000002008
 Product Name: Compressed Gauze
 Trade Name: N.A.
 Product Sizes: 11.43cm*3.75m
 Basic UDI-DI: 6974448150000B8
 EMDN Code: M03040101
 Classification
 Acc. to MDR Class Is, Rule 4
 Ax. VIII:
 Applied EN ISO 13485:2016 EN ISO 14971:2019/A11:2021 EN ISO 10993-1:2020
 Common
 Specification/ EN ISO 10993-5:2009 EN ISO 10993-10:2023 EN ISO 15223-1:2021
 standard: EN ISO 10993-23:2021 EN ISO 20417: 2021 EN 62366-1: 2015+A1:2020
 ENISO11607-1:2020 ENISO11607-2:2020 EN ISO 11135: 2014/A1:2019
 Conformity
 Assessment MDR Annex XI, Part A
 Procedure:
 Intended For use Compressed gauze is primarily intended for wound dressing in first - aid scenarios, such as cuts, scrapes, and minor bleeding. It can also be used in clinical settings for postoperative care to promote wound healing.

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR), any other relevant Union legislation that provides for the issuing of an EU declaration of conformity, any CS used and in relation to which conformity is declared and other relevant regulations. All supporting documentations are retained under the premises of the manufacturer.

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany

NB Identification Number: 0123

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CE Certificate No.: No. G21 044822 0009 Rev.00

Expire date of the Certificate: 2029-05-20

Start of CE Marking: 2024.08.15

Place of Issue: Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Date of Issue: 2024.08.14

Signature: 