Manufacturer	
Name and address:	Yancheng Zaichuang Medical Supplies Co., Ltd. 1 Fuda Road xintan town, Sheyang County, 224353 Yancheng City, P.R. China
Contact information:	19551290909
SRN:	CN-MF-000037590
European Authorized Representative	
Name and address:	MedPath GmbH Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
E-mail:	info@medpath.pro
SRN:	DE-AR-000000087
Notify Body	
Certification Body **Name**	TÜV SÜD Product Service GmbH
Address:	Ridlerstraße 65 80339 München
Country:	Germany
Notified Body Identification Number:	CE 0123
CE Certificate No.	**G20 123548 0002 Rev. 00**
Expire date of the Certificate	2030-05-18
Device information	
Device Name:	Non-sterile folded gauze
EMDN Code:	MO201020102-COTTON GAUZES, FOLDED, WITHOUT X-RAY DETECTABLE HREAD, NON-STERILE
Basic UDI-DI:	697676668ZSB4Z
Model and specification:	Please refer to the attachment
Intended use:	Non-Sterile Gauze Swabs used to absorb wound exudate and keep the wound dry.
Risk of classification:	Rule 4 (4.4, sentence 1) of Annex VIII of Regulation (EU) 2017/745
Conformity Assessment Procedure	Annex XI (Part A, Sec. 10) of Regulation (EU) 2017/745
Technical Document No.:	ZC/CE-MDR-09

We confirm our product can meet the requirement of Medical Device Regulation and the following harmonized standards:

EN ISO 13485:2016, EN ISO 15223-1:2021, EN ISO 20417-2021, EN ISO14971:2019, EN ISO 10993-1:2020, EN ISO10993-5:2020, ENISO10993-10:2023, EN ISO 10993-6:2016, EN ISO 10993-11:2018, EN ISO 10993-12:2012, EN ISO 10993-23:2020, EN ISO 10993-7:2008/AC:2009, EN ISO 11135: 2014, EN ISO 11737-1: 2018, EN ISO 11737-2: 2020, EN ISO 14079:2003

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). All supporting documentations are retained under the premises of the manufacturer.

Yan Cheng 2024.03.04 陈伟

Place, Date of Issue **Signature,**

盐城再创医疗用品有限公司

Position Yancheng zaichuang medical supplies Co., Ltd.