

**EU Declaration of Conformity**  
**According to ANNEX IV of the Medical Device Regulation (EU) 2017/745**

Manufacturer: GuangDong TiDaKang Medical Technology Co., Ltd.  
First Floor Area A, Third Floor Area A, Fourth Floor Area A, Fifth Floor Area A, No. 38 Jinjing Road, Pingnan Industrial Area, Sanxiang Town, Zhongshan City, 528463 Guangdong, P.R. China

SRN of the Manufacturer: CN-MF-000025927

Authorised Representative: MedPath GmbH  
Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

SRN of the Authorised Rep.: DE-AR-000000087

Product Name: Hydrocolloid Dressings

Product model: thin type、 Edge pressing type

Basic UDI-DI of Product: 697029610HDYK

Intended Purpose: Hydrocolloid dressings absorb wound exudate through water-soluble polymer particles. Used for covering and caring for wounds.

EMDN Code: M04040301

Classification (MDR, Annex VIII): **I, rule 1**

Conformity Assessment Procedure: **Annex II +Annex III of MDR**

We (manufacturer) herewith state that the above-mentioned product is in conformity with the following Regulations and standards. We are solely responsible for the EU declaration of conformity.

The applicable Medical Device Regulation and Product Standards:

Medical Device Regulation (EU) 2017/745

Standards:

ISO10993-1:2018, EN ISO10993-1:2009/AC:2010, EN ISO10993-5:2009, ISO10993-10:2023, EN ISO 10993-23:2021 ,EN ISO15223-1:2021 , EN 13726 :2023, EN ISO 13485:2016, EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021, EN ISO 14644-1:2015,EN ISO 14644-2:2015, ISO14698-2:2003/Cor1:2004,ISO 29862-2024, ASTM F 1980:2021, EN556-1:2001/AC2006, ISO 2859-1:1999 / md1:2011, MEDDEV2.7 /1 Rev. 4, EN 62366-1:2015 + AC:2015+A1 2020, ASTM D4169-16, ASTM F1929-23, ASTM F88: 23, Regulation (EU) 2018/1513.

Notified Body: /  
Identification number: /  
(EC) Certificate(s): Not applicable  
Expire date of the Certificate: /

Signature: \_\_\_\_\_ Robin Zhang  
Name: Robin Zhang  
Position: Legal representative  
Place, Date of Issue: 2025-01-03

