



Jinhua Jingdi Medical Supplies Co., Ltd.

EU Declaration of Conformity

1. Manufacturer: Jinhua Jingdi Medical Supplies Co., Ltd

Address: Building 2, Ditian Function Xiaoshun Town, Jindong Zone, 321000 Jinhua City, Zhejiang, People's Republic of China

2. EC-Representative: MedPath GmbH – Mies-van-der-Rohe-Strasse 8, 80807 Munich, GERMANY

3. Device group: M04 – Special dressings (Sterile wound dressing, Sterile Wound Plaster).

4. Classification (MDR 2017/745, Annex XI, part A): Medical Device class Is, Rule 4

5. Product

Brand name: BIODRESS

Product code	Basic UDI-DI (Barcode)	RDM
DRE12SBSR	8057014182989	2469260
DRE14SBSS	8057014182996	2469261
DRE15SBSS	8057014183849	2469264
DRE16SBSU	8034055912171	2469265
DRE25SBSU	8034055912188	2469266
DRE26SBSU	8034055912195	2469267
DRE27SBSU	8034055912201	2469268
DRE30SBSS	8057014183009	2469263
DRE36SBSS	8034055914892	2469262
DREG5SBSS	8057014186635	2469269

6. Statement:

We herein declare that the above-mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

7. DIRECTIVES

General applicable directives:

Medical Device Regulation: Regulation (EU) 2017/745 on Medical Devices (MDR) and subsequent amendments.

8. Standard Conformity:

EN ISO 15223-1 / EN ISO 13485 / EN ISO 14971

EN 13726 all applicable parts (EN 13726-1, EN 13726-2, EN 13726-3, EN 13726-4, others)

EN 556-1 / ISO 11135 / EN 868 all applicable parts (EN 868-2, others)

EN ISO 11607 all applicable parts (EN ISO 11607-1, EN ISO 11607-2, others)

EN ISO 10993 all applicable parts (EN ISO 10993-5, EN ISO 10993-7, EN ISO 10993-10, others)



Jinhua Jingdi Medical Supplies Co., Ltd.

9. Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße, 65, 80339 Munich, Germany

NB Identification number: 0123

10. (EC) Certificate(s) Number: G21 086533 0008 Rev. 00

Expire date of the Certificate: 2028-August-17

Date of Issue the certificate: 2023-August-18

Name and Surname Xu Xinhai

Qualification: General Manager

Date: 2023-August-18

Stamp and Signature

金华市景迪医疗用品有限公司
JINHUA JINGDI MEDICAL SUPPLIES CO., LTD