

EU Declaration of Conformity

Manufacturer: FIRSTAR HEALTHCARE COMPANY LIMITED (GUANGZHOU)
Address: Rm. 901, Building No.2, Headquarters Center, Tian'an High-tech Ecological
Park, Panyu, 511400 Guangzhou, PEOPLE'S REPUBLIC OF CHINA
SRN: CN-MF-000009645

European: MedPath GmbH
Representative: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
SRN: DE-AR-000000087

Trade name: FIRST AID DRESSING
Product Name: FIRST AID DRESSING
Product code: 390163, 390170, 390149, 390156, FS-8030, FS-8031, FS-8020, FS-8021
EMDN code: M03030101
Intended use: Applicable for hemostasis to trauma and isolating wound in first-aid.

Applied Standard & Common Specification:

EN 14079:2003, EN ISO 14971:2019, EN ISO 14971:2019/A11:2021, EN ISO 13485:2016, EN
ISO13485:2016/AC:2018, EN ISO 13485:2016/A11:2021

Basic UDI-DI: See attached.

Classification acc. to MDR Annex VIII: Class Is, Rule 4

Conformity assessment procedure: Annex XI Part A of MDR(EU)2017/745

Name of the Notified Body: TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße.
65 • 80339, 80339 Munich • Germany

NB Identification number: 0123

CE certificate No: G21 047330 0062 Rev.01

Expiry date of the certificate: 2028-02-08

Start of CE Marking: 2024-08-02

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.

Signature: *Janice-Li*

Name: Janice-Li

Position: QM

Place: Guangzhou

Date: 2024-09-10

Document No: FS-MDR/TD-02(10)
Version: 01

Attached:

Basic UDI-DI:

SN	Models	Basic UDI-DI
1	390163	69422726P3.02.31XC
2	390170	69422726P3.02.42XH
3	390149	69422726P3.02.62XP
4	390156	69422726P3.02.41XF
5	FS-8030	69422726P3.02.33XG
6	FS-8031	69422726P3.02.33XG
7	FS-8020	69422726P3.02.30XA
8	FS-8021	69422726P3.02.30XA