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 Representative: MedPath GmbH

Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

SRN: DE-AR-000000087

Trade name: PLASTER DRESSING

Product Name: Adhesive Plaster

Product code: FS-200P、FS-200F、FS-202P、FS-202F、FS-203P、FS-203F、FS-204P、FS-204F、FS-205P、FS-205F、FS-207P、FS-207F、FS-222P、FS-222F、FS-208P、FS-208F、FS-240

Intended use: Act as a barrier, maintain wound position and absorb exudates from the wound.

Applied Standard & Common Specification:	EN ISO 14971:2019, EN 13726-1:2002/AC:2003
Basic UDI-DI:	69422726P2.02.11WM
Classification acc. to MDR Ax .VIII:	Class I, Rule 1
Conformity assessment procedure:	Annex II +Annex III of MDR

CE certificate No: N.A

Name and ID of the Notified Body: N.A

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: 2024.1.26

Declaration of Conformity

Manufacturer: RFX + CARE Manufacturing Co., Ltd.
Address: 7 Lanjiang Road, Yuecheng District, Shaoxing, P. R. China

EC-Representative: RFX+Care International A/S
Address: Bakkegaardsvej 408, 3050 Humlebaek, Denmark

Product Name: Cleansing swab and Tube
Specifications: 12x15cm, 12.5x18cm; 15ml, 20ml, 30ml, 500ml
UMDNS Code: 37207
Classification of Product: Class IIa, Rule 5
Conformity Assessment Route: **Annex V.3**
We herewith 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.
RFX + CARE Manufacturing Co., Ltd. is exclusively responsible for the declaration of conformity.

Medical Device Directives and Regulation

General applicable directives:
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007.
Regulation (EU)2023/607 of the European parliament and of the council of15 March 2023

Notified Body: TÜV SÜD Product Service GmbH,
Ridlerstrasse 65, 80339 München, Germany
NB Identification number: 0123
(EC) Certificate(s): G2 067759 0023 Rev.00
Expire date of the Certificate: 2028-12-31
Start of CE Marking: 2015-04-30
Place, Date of Issue: Shaoxing, 2024-02-19

General Manager (Signature): _____

Revision Records:

S/N	Edition /Revision	Revision Content	Issued Date
1	02	Add CE Certificate	2015-08-06
2	03	Revise Specifications	2016-08-25
3	04	Updated the certificate information	2018-02-09
4	05	Update certificate information	2018-11-23
5	06	Add CE certificate version	2021-04-22
6	07	Add new Medical Device Regulation, update the expire date of the certificate.	2024-02-19
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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 Representative: MedPath GmbH
Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

SRN: DE-AR-000000087

Trade name: ELASTIC BANDAGE

Product name: ELASTIC BANDAGE

Product code: FS-3450、FS-3451、FS-3452、FS-3453、FS-3549、FS-3554、FS-3560、FS-3561、FS-3562、FS-3563、FS-3570、FS-3571、FS-3572、FS-3573、FS-3590、FS-3591、FS-3592、FS-3593

Intended use: It is used to provide binding force to wound dressing or limbs for bandaging and fixation.

Applied Standard & Common Specification: EN ISO 14971:2019

Basic UDI: 69422726P3.02.08XH

Classification acc. to MDR Ax .VIII: Class I, Rule 1

Conformity assessment procedure: Annex II +Annex III of MDR

CE certificate No: N.A

Name and ID of the Notified Body: N.A

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: 2023.10.12

EU Declaration of Conformity

Manufacturer: FIRSTAR HEALTHCARE COMPANY LIMITED (GUANGZHOU)

Address: Rm. 901, Building No.2, Headquarters Center, Tian'an High-tech EcologicalPark, Panyu, 511400 Guangzhou, PEOPLE'S REPUBLIC OF CHINA

SRN: CN-MF-000009645

European Representative: MedPath GmbH

Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

SRN: DE-AR-000000087

Trade name: MEDICAL GLOVES

Product Name: MEDICAL GLOVES

Intended use: It is used to wear on the doctor's hand or finger to check or touch the patient's condition, or to prevent the doctor's hand from being bitten.

Material	EMDN code	Product code	Size
Nitrile	T01010202	FS-353	Small、Medium、Large、X-Large
Powdered latex	T01010101	FS-348	
Non-powdered latex	T01010102	FS-349	
Vinyl gloves	T01020201	FS-350、FS-352	

Applied Standard & Common Specification: EN 455-1:2000、EN 455-2:2009+A2:2013、EN 455-3:2006、EN 455-4:2009

Basic UDI: 69422726P4.04.01Y2

Classification acc. to MDR Ax .VIII: Class I, Rule 1

Conformity assessment procedure: Annex II +Annex III of MDR

CE certificate No: N.A

Name and ID of the Notified Body: N.A

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

Place: GuangZhou

Name: Janice-Li

Date: 2024.2.23

Position: QM

EU Declaration of Conformity

Manufacturer: FIRSTAR HEALTHCARE COMPANY LIMITED (GUANGZHOU)

Address: Rm. 901, Building No.2, Headquarters Center, Tian'an High-tech EcologicalPark, Panyu, 511400 Guangzhou, PEOPLE'S REPUBLIC OF CHINA

SRN: CN-MF-000009645

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

SRN: DE-AR-000000087

Trade name: MEDICAL TAPE

Product Name: MEDICAL TAPE

Product code: FS-3100、FS-3101、FS-3104、FS-3105、FS-3141、FS-3081

Intended use: It is used to paste and fix the dressing on the wound or fix other medical devices to specific parts of the human body.

Applied Standard & Common Specification:	EN ISO 14971:2019
Basic UDI:	69422726P2.08.01XU
Classification acc. to MDR Ax .VIII:	Class I, Rule 1
Conformity assessment procedure:	Annex II +Annex III of MDR

CE certificate No: N.A

Name and ID of the Notified Body: N.A

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: 2023.10.20

Declaration of Conformity

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

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

Product: Sterile Gauze Sponges
Model code: 2"×2",3"×3",4"×4"

Classification (MDD, Annex IX): Is, Annex IX Rule 4
Conformity assessment route: Annex V

We are exclusively responsible for the above mentioned products meet the provisions of the following EC council Directive and standards The products meet prospective use sand all supporting documentations are retained under the premises of the manufactures.

DIRECTIVES

General applicable directives:
Medical device directive: Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC), amended by 2007/47/EC.

Standards Applied:
Harmonized standards published in the official journal of the European communities applicable to this product.
Notified Body: TUV SUD Product service GmbH,Ridlerstr.65,D-80339 Munich,Germany.
NB Identification number: 0123
Certificate: GCQ 047330 0065 Rev.00
Expiry data of the Certificate:2024-05-26
Start of CE Marking:2019-10-21
Place, date of issue: Rm. 901, Building No.2, Headquarters Center, Tian'an High-tech Ecological Park, Panyu, Guangzhou,China.

Signature Janice-Li
Name: Janice-Li
Position: SQM
Date: 2023.8.30

HEALTHCARE COMPANY LIMITED 广州市富施达医疗器械有限公司

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 Representative: MedPath GmbH

Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

SRN: DE-AR-000000087

Trade name: TRIANGULAR BANDAGE

Product name: TRIANGULAR BANDAGE

Product code: FS-143、FS-140N、FS-142N、FS-143S、FS-140、FS-140L、FS-140K

Intended use: Used for wound dressings or limbs to provide binding force to play a role in bandaging, fixation.

Applied Standard & Common Specification:	EN ISO 14971:2019
Basic UDI:	69422726P3.05.05XY
Classification acc. to MDR Ax .VIII:	Class I, Rule 1
Conformity assessment procedure:	Annex II +Annex III of MDR

CE certificate No: N.A

Name and ID of the Notified Body: N.A

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: 2023.10.9

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

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

Product: Wound Dressing
Model code: 5×8、6×7、6×10、8×15、9×10、9×15、10×12、10×20、10×25、10×30、10×35、10×40、12×12、12×14、8×10cm

Classification (MDD, Annex IX): Is, Annex IX Rule 4
Conformity assessment route: Annex V

We are exclusively responsible for the above mentioned products meet the provisions of the following EC council Directive and standards The products meet prospective use sand all supporting documentations are retained under the premises of the manufactures.

DIRECTIVES

General applicable directives:
Medical device directive: Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC), amended by 2007/47/EC.

Standards Applied:
Harmonized standards published in the official journal of the European communities applicable to this product.
Notified Body: TUV SUD Product service GmbH,Ridlerstr.65,D-80339 Munich,Germany.
NB Identification number: 0123
Certificate: GCQ 047330 0065 Rev.00
Expiry data of the Certificate:2024-05-26
Start of CE Marking:2019-10-21
Place, date of issue: Rm. 901, Building No.2, Headquarters Center, Tian'an High-tech Ecological Park, Panyu, Guangzhou,China.

Signature Janice-Li
Name: Janice-Li
Position: SQM
Date: 2023.8.30

FIRSTAR HEALTHCARE COMPANY LIMITED (GUANGZHOU) 广州市富施达医疗器械有限公司