



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 045790 0026 Rev. 01

Manufacturer

**Hubei Qianjiang Kingphar
Medical Material Co., Ltd.**

Yuanguang Road
433100 Qianjiang
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

**Sterile Gauze Swab without X-ray Detectable,
Sterile Gauze Ball without X-ray Detectable,
Sterile Bandage,
Sterile Non-woven Swab,
Sterile Gauze Roll,
Absorbent Cotton,
Disposable Non-woven Wearing**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH1901223

Valid from: 2019-08-16

Valid until: 2024-04-13

Date, 2019-08-16

Stefan Preiß
Head of Certification/Notified Body



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Facility(ies):

Hubei Qianjiang Kingphar Medical Material Co., Ltd.
Yuanguang Road, 433100 Qianjiang, PEOPLE'S REPUBLIC OF
CHINA

Hubei Qianjiang Kingphar Medical Material Co., Ltd.
No. 272 Hongjun Road, 433100 Qianjiang, PEOPLE'S REPUBLIC
OF CHINA

ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ CERTIFICADO ♦ CERTIFICAT

HUBEI QIANJIANG KINGPHAR MEDICAL MATERIAL CO LTD

NO	NAME	SIZE	CLASSIFICATION	Rule	UMDNS Codes	CERT.NO	Sold date first time with own CE mark
1	Sterile Non-woven Swab	5×5cm,4p/6p/8p	I sterile	4	13695	G2S 045790 0026 Rev. 01	Not yet
		7.5×7.5cm,4p/6p/8p					
		10×10cm,4p/6p/8p					
		10×20cm,4p/6p/8p					
2	Sterile Gauze Ball without x-ray Detectable	6×6cm,8cm×8cm	I sterile	4	13700	G2S 045790 0026 Rev. 01	Not yet
		10×10cm,12×12cm					
		15×15cm,20×20cm					
		25×25cm,30×30cm					
		30×40cm,40×50cm					
3	Sterile Gauze Swab without x-ray Detectable	5×5cm,8p/12p/16p	I sterile	4	10966	G2S 045790 0026 Rev. 01	Not yet
		7.5×7.5cm,8p/12p/16p					
		10×10cm,8p/12p/16p					
		10×20cm,8p/12p/16p					
		10×13cm,12p/16p					
		8×18cm,16p;20×20cm,16p					
		7.5×9cm,16p;25×25cm,16p					
		12.5×20cm,16P					
4	Sterile Bandage	4cm×4.1y/4.5y/5y	I sterile	4	10274	G2S 045790 0026 Rev. 01	Not yet
		6cm×4.1y/4.5y/5y					
		8cm×4.1y/4.5y/5y					
		10cm×4.1y/4.5y/5y					
		12cm×4.1y/4.5y/5y					
		15cm×4.1y/4.5y/5y					
5	Sterile Gauze Roll	36"×100y-1p/2p/4p	I sterile	4	11859	G2S 045790 0026 Rev. 01	Not yet
		47"×100y-1p,39"×100y-1p					
		44"×100y zig-zag					
		36"×100y zig-zag					
		1",2",3",4",6"					
6	Absorbent Cotton	0.2g 0.4g 0.5g10g	I sterile	4	13414	G2S 045790 0026 Rev. 01	Not yet
		3"X0.2" 3"X0.3"					
		6"X0.2"6"X0.3"6"X0.4"					
		25g 50g 100g					
		250g 450g 500g					

Elaborator:

Audit:

Approval:

Date:

Date:

Date:

湖北省潜江市江泰医用材料有限公司
HUBEI QIANJIANG KINGPHAR MEDICAL MATERIAL CO.,LTD.

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NO	NAME	SIZE	CLASSIFICATION	Rule	UMDNS Codes	CERT.NO	Sold date first time with own CE mark
7	Disposable Non-woven Wearing	Non-woven gown	I sterile	4	12447	G2S 045790 0026 Rev. 01	Not yet
		M、L、XL、XXL、XXXL					
		Non-woven cap					
		S、M、L					
		Non-woven shoe cover					
		S、M、L					
		Non-woven face mask					
		S、M、L					

湖北省潜江市江赫医用材料有限公司
HUBEI QIANJIANG KINGPHAR MEDICAL MATERIAL CO.,LTD.

Elaborator: 马林
Date: 2020.01.05

Audit: 王明
Date: 2020.01.05

Approval: 王明
Date: 2020.01.05