

**CE EC Declaration of Conformity CE**

**According to the Medical Device Directive 93/42/EEC.**

**Manufacturer's Name:** JIANGSU JIELE MEDICAL DRESSING CO.,LTD

**Manufacturer's Address:** 15# HUANXI RD DIAOPU TOWN TAIZHOU, JIANGSU CHINA

**EC-Representative:** ROVAL MED S.R.L ROMANIA  
Industriilor, Nr. 2M, Sector 3,  
032891 Bucharest,  
Romania.

**Name of Device:** GAUZE BANDAGE

**Products Class:** Class Ia

**Name of Device:** GAUZE ROLL

**Products Class:** Class Ia

**Name of Device:** STERILE GAUZE SWABS (SPONGES)

**Products Class:** Class I\* (I Sterile )

**Batch No:** 20160710

**Brand Name :** Help

**Name of Device:** ABSORBENT ZIGZAG GAUZE FOLDED

**Products Class:** Class Ia

We, the undersigned and stamped, hereby declare that the medical device(s) specified above conform to the Essential Requirements list in Directive 93/42/EEC.

**This declaration is based on:** Annex V of the Directive 93/42/EEC on Medical Devices

**Competent Authorized:** TUV Rheinland LGA Products GmbH  
Tillystrabe 2-90431 Nurnberg, Germany.

**NB identification number:** 0197

**Registration Date:** 07.16.2012

**Registration No.:** DD 60077422 0001

Jiangsu, China.AUG.25, 2016.

(Place)

(Date)

JIANGSU JIELE MEDICAL DRESSING CO.,LTD

(Company stamp and legal signature)



## JIANGSU JIELE MEDICAL DRESSING CO., LTD.

## TEST REPORT

INVOICE NO: JL160011		LOT: 20160710
Test Basis BP98		
Name: sterile gauze swab		
Size: 10cm x 8cm		
Item	Standard	Result
Thread count		23 x 13
Yarn Count (Warp x Wet)		40s/40s
Weight		20.1
Weiteness	$\geq 80$	83
Breeding Load/Warp	$\geq 10.9N$	62
Breeding Load/Weft	$\geq 23.6N$	35
Fluorescence	No	No
Loss On Drying	$\leq 8\%$	5.2%
Sinking Time	$\leq 10s$	3.5s
Acidity or Aikalinity	Not Appear Pink	No
Stach and Dextrin	No red vioter or blue color	No
Ignited	$\leq 0.4\%$	0.15%
Extractable	No Blue Green Color	No
Water-soluble Substances	$\leq 0.5\%$	0.21%
Surface Active Substances	$\leq 2mm$	1.3mm
Ether-soluble Substances	$\leq 1.5\%$	1.1%
Ethyl Oxide Residuals	product set should be $\leq$ less	pass
Free of Bacteria	It should be free of bacteria.	pass
Free of Pyrogen	It should be free of pyrogen.	pass
Sterility Control	the technical requirements	pass
Comment	<input type="checkbox"/> Acceptable <input type="checkbox"/> Unacceptable	

Inspected By: zongchuangwang

Date: 2016-08-22

Reviewed By: yaojie

Date: 2016-08-22

