DECLARATION OF CONFORMITY

CE

Product: **STERILE GAUZE SWAB**
Classification: **Class II a**

We hereby declare that all the above mentioned products meet the provisions of the council directive 93/42/EEC for Medical Device Directive.

General Applicable Directives:

Medical Device Directive council directive 93/42/EEC of June 1993 concerning medical devices. (MDD93/42/EEC).

Standards:

EN 980:1996/A1: 1999	Graphical symbols for use in the labeling of medical devices
EN 1041:1998	Information supplied by the manufacturer with medical devices
EN 14971:2000	Risk management

Date of Issue: **14/03/2007**

Signature :

Name : **Chen Guoping**

Position : **General Manager**

Declaration of Conformity

Manufacture: Allmed Medical Product s Co, Ltd
Address: Room 1911, Hanggang Fuchun Business Building,
6031st Shennan Middle Road, Shenzhen City, 518040,
European Representative:Shanghai International Holding Corp. GmbH (Europe)
Addr: Eiffestrasse 80, 20537, Hamburg, Germany

Product Name: Sterile Medical Pack, Medical dressings / please see List of CE-labeled Products
Model Number: Please see List of CE-labeled Products
UMDNS Code: Please see List of CE-labeled Products

Classification (MDD, Annex IX): Please see List of CE-labeled Products
Conformity Assessment Route: MDD93/42/EEC Annex V.

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.

DIRECTIVES

General applicable directives:
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Standard Applied: See attached list of (harmonized – EN) standards for which documented evidence of compliance can be provided.

Notified Body: TÜV Product Service GmbH, Ridlerstr. 65, 80339
MÜnchen, Germany

Identification number: CE0123
(EC) Certificate(s): **G2 04 08 53379 002** **G2S 06 03 53379 005**
Expire date of the Certificate: **2009-09-08**
Start of CE Marking: **2004-09-09** (only for those manufacturers which has already put their own CE mark on the products)

Allmed Medical Products Co. Ltd.

07.6.26
Date / Signature of Quality or Regulatory Affairs representative

ALLMED MEDICAL PRODUCTS CO., LTD

Document No.: WI-CE-010

Control Status: Valid

List of CE-labeled Products

S/N	Name of Product	Models/Sizes/Types	Classification	Rule of classification	Date of first CE-marking
1	Sterile/Non-Sterile Laparotomy Sponges(with X-ray, without X-ray)	4"x18"-4P 12"x12"-4P 18"x18"-4P 18"x36"-4P 22.5x22.5cm-12p , X-ray 30x30cm-12p , X-ray 30x30cm-24p , X-ray 45x45cm-6p , X-ray 45x45cm-12p , X-ray	IIa	Rule 6	2004.09.09
2	Sterile/Non-Sterile X-Ray Detectable Woven Gauze Sponges	3"x3"-12p , X-ray 4"x4"-12p , X-ray 4"x4"-16p , X-ray 4"x4"-32p , X-ray 8"x4"-12p , X-ray 8"x4"-16p , X-ray 8"x4"-24p , X-ray 10x7.5cm-32p , X-ray 15x2.5cm-16p , X-ray 15x10cm-24p , X-ray 30x30cm-18p , X-ray 36x11cm-16p , X-ray 10x10cm-12p , X-ray	IIa	Rule 6	2004.09.094
3	Sterile/Non-Sterile Woven Gauze Sponges	2"x2"-8P 2"x2"-12P 3"x3"-8P 3"x3"-12P 4"x4"-8P 4"x4"-12P 4"x4"-16P 4"x8"-8P 4"x8"-12P	I	Rule 4	2004.09.09
4	Sterile/Non-Sterile Non-Woven Sponges	2"x2"- 4P 3"x3"-4P 4"x4"-4P 4"x8"-4P 2"x2"-6P 4"x4"-6P	I	Rule 4	2004.09.09

5	Sterile/Non-Sterile Drain Sponges	2"x2"-6P 4"x4"-6P 4"x4"-16P	I	Rule 4	2004.09.09
6	Sterile/Non-Sterile Post-Op Sponges	4"x3"-8P 4"x4"-8P	I	Rule 4	2004.09.09
7	Sterile/Non-Sterile ABD Pads	5"x9" 8"x7.5" 8"x10"	I	Rule 4	2004.09.09
8	Sterile/Non-Sterile Fluffy Gauze Bandages	2"x3y-1p 3"x3y-1p 4"x3y-1p 3"x2.1y-1p 4"x2.1y-1p 2"x3.6y-2p 3"x3.6y-2p 4"x3.6y-2p 6"x3.6y-2p 2"x3.5y-3p 3"x4.1y-3p 4"x4.1y-3p 6"x4.5y-3p 4.5"x4.1y-6p 3.4"x4.1y-6p 3.4"x3.1y-6p 3.4"x3.6y-6p 4.5"x4.1y-8p	I	Rule 4	2004.09.09
9	Sterile/Non-Sterile Fluffy Gauze Sponges	6"x6.75" 7.75"x8.75" 4"x4"-12P	I	Rule 4	2004.09.09
10	Sterile/Non-Sterile Cotton-Filled Exodontias Sponges	2"x2"-8P 3"x3"-8P 4"x4"-8P	I	Rule 4	2004.09.09
11	Sterile/Non-Sterile Gauze	5cm(min)~150cm(max)	I	Rule 4	2004.09.09
12	Sterile/Non-Sterile Sterile Medical Pack		I	Rule 4	2004.09.09
13	Sterile/Non-Sterile Conforming stretch gauze	2"x4.1y-1p 3"x4.1y-1p 4"x4.1y-1p 6"x4.1y-1p	I	Rule 4	2004.09.09
14	Sterile/Non-Sterile Eye Pads	1 5/8" x 2 3/8" 2 1/8" x 2 5/8"	I	Rule 4	2004.09.09
15	Sterile/Non-Sterile Topper Sponges	4"x3"-8P 4"x4"-8P	I	Rule 4	2004.09.09
16	Sterile/Non-Sterile Cotton Rolls	1Lb Cotton Roll	I	Rule 4	2004.09.09

Filled by: Joy Liu (Signature/Stamp)

Approved by: Andy Law (Signature/Stamp)

Date: 2007-06-20

No. AM20100008

Declaration of Conformity

Manufacture: Allmed Medical Product s Co, Ltd

Address: Room 1911,Hanggang Fuchun Business Building,6031th Shennan Middle Road,Shenzhen 518040, P. R. C.

European Representative: Shanghai International Trading Corp. GmbH (Hamburg)

Address: Eiffestrasse Eiffestrasse 80, 20537 Hamburg, Germany

Product Name: Woven Gauze Sponges ,Fluff Gauze Sponges
UMDNS Code: 13700
Model Number: Please refer to List of CE-labeled Products.
Classification (MDD, Annex IX): I sterile
Conformity Assessment Route: MDD93/42/EEC Annex V, section 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.

DIRECTIVES

Medical Device Directive: The object of the declaration described above is in conformity with the Council Directive MDD 93/42/EEC amended by 2007/42/EC.

Standard Applied: All applicable harmonised standard (published in the official journal of the European Communities).

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 MÜnchen, Germany
Identification number: CE0123
(EC) Certificate(s): **G2S 10 05 53379 006**
Expire date of the Certificate: **2014-09-08**
Start of CE Marking: **200X-XX-XX** (Not start)
Place, Date of Issue: **Guangdong, 2010-9-15**

Signature: 华敬涛 2010.9.15 Name:

Director of Corporate QA & RA Position:

No. AM20130003

Declaration of Conformity

Manufacture: Allmed Medical Product s Co, Ltd

Address: West Gong Yuan Road, Majiadian Town, 443200 Zhijiang City, Hubei Province, PEOPLE'S REPUBLIC OF CHINA

European Representative: Shanghai International Trading Corp. GmbH (Hamburg)

Address: Eiffestrasse Eiffestrasse 80, 20537 Hamburg, Germany

Product Name: Fluffy Gauze Bandages, Triangular Bandages
UMDNS Code: 10281
Model Number: Please refer to List of CE-labeled Products.
Classification (MDD, Annex IX): I sterile
Conformity Assessment Route: MDD93/42/EEC Annex V.

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.

DIRECTIVES

Medical Device Directive: The object of the declaration described above is in conformity with the Council Directive MDD 93/42/EEC.

Standard Applied: All applicable harmonised standard (published in the official journal of the European Communities).

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 MÜnchen, Germany
Identification number: CE0123
(EC) Certificate(s): **G2S 13 07 53380 004**
Expire date of the Certificate: **2014-09-08**
Start of CE Marking: **200X-XX-XX** (Not start)
Place, Date of Issue: **Hubei,2013-8-1**

Signature: _____ 2013-08-30

Name:

QA manager

Position:

No. AM201400019

Declaration of Conformity

Manufacture: Allmed Medical Product s Co, Ltd

Address: No.180 GongYuan Road, Majiadian Town,443200Zhijiang City, Hubei province, PEOPLE' S REPUBLIC OF CHINA

European Representative: Shanghai International Holding Corp. GmbH(Europe)

Address: Eiffestrasse Eiffestrasse 80, 20537 Hamburg, Germany

Product Name: Sterile and non-sterile zig zag (folded) gauze (with or without x-ray therad)
UMDNS Code: 11859
Model Number: Please refer to List of CE-labeled Products.
Classification (MDD, Annex IX): IIa
Conformity Assessment Route: MDD93/42/EEC Annex V.

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.

DIRECTIVES

Medical Device Directive: The object of the declaration described above is in conformity with the Council Directive MDD 93/42/EEC.

Standard Applied: All applicable harmonised standard (published in the official journal of the European Communities).

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 MÜnchen, Germany
Identification number: CE0123
(EC) Certificate(s): G2 14 09 53380 011
Expire date of the Certificate: 2019-12-29
Start of CE Marking: **2012-1-18**
Place, Date of Issue: **Hubei,**2014-12-30

Signature: _____ 2014-12-30

Name:

QA Manager

Position:

Declaration of Conformity

1. Manufacturer: Xuchang Zhende Surgical Dressing Co., Ltd.
   Yanling County Private-owned Enterprises Industrial Area
   461200 Xuchang, Henan, PEOPLE'S REPUBLIC OF CHINA
2. EC Representative: Shanghai international Holding Corp. GmbH (Europe)
   Eiffestrasβe 80 20537 Hamburg Germany
3. Product name: Sterile Gauze Swabs without X- ray Thread
   UMDNS Code: 13700
4. Classification (MDD, Annex IX): I sterile rule 4
   Conformity Assessment Route: Annex Ⅴ section 3
   Statement:
   We, the manufacturer, herewith declare under our sole responsibility that the above mentioned products meet the provision of the EC Council Directives and standards. All supporting documents are retained under permises of the Authorized Representative.
5. DIRECTIVES
   General applicable directives:
   Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC)
   Standard applied:
   All applicable harmonized standards
6. Notified Body: TüV SüD Product Service GmbH,
   Ridlerstrasse 65·80339 München, Germany
   NB Identification number: 0123
7. (EC) Certificate(s): G2S 13 12 60249 011
8. Start of CE Marking: 2014-03-04
9. Expire date of the Certificate: 2019-03-03

Place, Date of Issue: Xuchang, 2014-02-20

Signature: 王冰新 Date: 2014-02-20

Name: Wang bingxin Position: General Manager

1. Products

Class I: Non-sterile Gauze Products (without X-ray detectable element)

Swabs / Sponges (plain and fluff), Lap sponges (washed, unwashed and fluff), Balls, Rolls, O.R. Towels, Trach sponges, Handkerchief.

Class I sterile: Sterile Gauze Products (without X-ray detectable element)

Swabs / Sponges (plain and fluff), Lap sponges (washed, unwashed and fluff), Balls, Rolls, O.R. Towels, Trach sponges, Handkerchief.

Class IIa: Non-sterile and Sterile Gauze Products (with X-ray detectable element)

Swabs / Sponges (plain and fluff), Lap sponges (washed, unwashed and fluff), Balls, Rolls.

Class IIa: Non-sterile and Sterile Gauze Products (without X-ray detectable element)

Swabs / Sponges (plain and fluff), Lap sponges (washed, unwashed and fluff)

2. Manufacturer

Name: Winner Industries (Shenzhen) Co., Ltd.

Address: Winner Industrial Park, No.660 Bulong Road, Longhua District 518109, Shenzhen, CHINA

3. EC-Representative

Name: Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestraße 80, 20537 Hamburg, Germany

4. Notified Body

Name: TÜV SÜD Product Service GmbH

Identification No.: 0123

Address: Zertifizierstelle, Ridlerstrasse 65, 80339 München, GERMANY

5. Statement

We hereby declare that above mentioned products with CE marking meet the provisions of Medical Device Directive (Council directive 93/42/EEC of 14 June 1993 concerning medical devices as amended by directive 2007/47/EC).

6. Applicable Standards

EN ISO 13485:2012, EN ISO 14971:2012, EN ISO 15223-1:2012, EN 1041:2008, ISO 2859-1-1999, EN ISO 10993-1:2009/Ac:2010, EN ISO 10993-5:2009, EN ISO 10993-7:2008/Ac:2009, EN ISO 10993-10:2010, EN ISO 10993-12:2012, EN ISO 11135-1:2007, EN ISO 11135-2:2008, ISO 11135:2014, EN ISO 11137-1:2006/A1:2013, EN ISO 11137-2:2013, EN ISO 11138-2:2009, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 11737-1:2006/Ac:2009, EN ISO 11737-2: 2009, ISO 14644-1:1999, EN 14079:2003

7. Conformity Assessment Procedures

EC declaration of conformity (Annex VII) of Council directive 93/42/EEC concerning medical devices for Class I (Non-sterile) medical devices.

EC declaration of conformity (Annex VII) + Production quality assurance (Annex V) of Council directive 93/42/EEC concerning medical devices for Class I (Sterile) medical devices.

Full quality assurance (Annex II) section 3 of Council directive 93/42/EEC concerning medical devices for Class IIa medical devices.