



EC Declaration of Conformity

**Directive Council Directive 93/42/EEC of 14 June 1993
concerning medical devices including Directive 2007/47/EC**

Applicant

Name: Wuhan Aimmax Trade Co., Ltd.

Address: NO.5, Yale Building of Guanshan Chunxiao, Guanshan 1Rd, East Lake Developing Zone, Wuhan, China.

Product

Name: Gauze Swab, Absorbent Gauze Roll, Laparotomy Sponge, Cotton Wool, Cotton Ball, Face Mask, Isolation Gown, Lab Coat, Coverall, Surgical Gown, Scrub Suit, Shoe Cover, Caps(Hoods), Apron, Bed Sheet, Dental Bibs, Underpad, Earphone Cover, Sleeve, Panty, Beard Cover, Glove, Non woven Roll, Non woven Swab, Bandages, Surgical Pack

Type: See Annex of details

Classification: Class I

Rule: According to Rule 1

We confirm our product can meet the requirement of Medical Device Directive(93/42/EEC) and the following harmonized standards.

EN ISO 14971:2012

EN ISO 15223-1:2016

EN 1041:2013

EN ISO 10993-1:2009/AC:2010

EN ISO 10993-5:2009

EN ISO 10993-10:2013

EN 14683:2014

Signature:



Date: 2019/12/15

Annex

NO.	Product Name	Type
1	Gauze Swab	5x5cm,7.5x7.5cm,10x10cm,10x12.5cm,15x15cm,10x20cm,any size can be customized
2	Absorbent Gauze Roll	12*8,17*9,17*10,18*8,18*10,19*10,19*14,19*15,20*12,22*18,24*20,25*15,25*17,26*18,28*24,30*20,any size and any mesh can be customized
3	Laparotomy Sponge	30x30cm,40x40cm,45x45cm,50x60cm,10x90cm,any size can be customized
4	Cotton Wool	25g, 50g, 100g, 150g, 200g, 250g, 500g, 1000g,any size can be customized
5	Cotton Ball	0.1g/pc, 0.2g/pc, 0.5g/pc, 1.0g/pc, 1.5g/pc, 2.0g/pc,any size can be customized
6	Face Mask	17.5x9.5cm,(Ear loop or with Tie On),any size can be customized
7	Isolation Gown	XS,S,M,L,XL,XXL,XXXL,XXXXL
8	Lab Coat	XS,S,M,L,XL,XXL,XXXL,XXXXL
9	Coverall	XS,S,M,L,XL,XXL,XXXL,XXXXL
10	Surgical Gown	XS,S,M,L,XL,XXL,XXXL,XXXXL
11	Scrub Suit	XS,S,M,L,XL,XXL,XXXL,XXXXL
12	Shoe Cover	15x36cm,16x38cm,15x41cm,17x41cm,17x43cm,18x40cm,any size can be customized
13	Caps(Hoods)	(18",19",21",24"),(9g -- 30g) ,(15mic-50mic),(Single elastic, Double elastic) ,any size can be customized
14	Apron	S,M,L,XL,XXL,XXXL,XXXXL,24"x42",28"x46",any size can be customized
15	Bed Sheet	80x180cm,120x180cm,120x220cm,120x240cm,any size can be customized
16	Dental Bibs	33x45cm,40x45cm,any size can be customized
17	Underpad	60x60cm,60x90cm,any size can be customized
18	Earphone Cover	6.5cm,9cm,11cm,13cm,any size can be customized
19	Sleeve	20x40cm,20x42cm,20x46cm,22x46cm,any size can be customized
20	Panty	M,L,XL,XXL,any size can be customized
21	Beard Cover	18",19", 21", 24",any size can be customized
22	Glove	S,M,L,XL
23	Non woven Roll	10cm,15cm,16cm,17.5cm,18.5cm,any size can be customized
24	Non woven Swab	Size:5x5cm,7.5x7.5cm,10x10cm,10x20cm,2"x2",3"x3",4"x4",4"x8",any size can be customized; Layer: 4ply,8ply,12ply,16ply



25	Bandages	2.5cmx4.5m,5cmx4.5m,7.5cmx4.5m,10cmx4.5m,15cmx4.5m, any size can be customized
26	Surgical Pack	20x13.5cm,16x11cm,14x10cm,12x9.3cm,18x13x7cm,22x15x7 cm,any size can be customized

Handwritten signature in blue ink.

