



Compliance Report

Applicant: Wuhan Aimmax Trade Co., Ltd.
Address: NO.5, Yale Building of Guanshan Chunxiao, Guanshan 1Rd,
East Lake Developing Zone, Wuhan, China.

Product: 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 for details

Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. 02995
Initial Issue Date: 27 Nov 2018

Tony Chen

General Manager (Signature)



Annex to Report (No. 02995)

Wuhan Aimmax Trade Co., Ltd.

Product Name	Type
Gauze Swab	5x5cm, 7.5x7.5cm, 10x10cm, 10x12.5cm, 15x15cm, 10x20cm, any size can be customized
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
Laparotomy Sponge	30x30cm, 40x40cm, 45x45cm, 50x60cm, 10x90cm, any size can be customized
Cotton Wool	25g, 50g, 100g, 150g, 200g, 250g, 500g, 1000g, any size can be customized
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
Face Mask	17.5x9.5cm, (Ear loop or with Tie On), any size can be customized
Isolation Gown	XS, S, M, L, XL, XXL, XXXL, XXXXL
Lab Coat	XS, S, M, L, XL, XXL, XXXL, XXXXL
Coverall	XS, S, M, L, XL, XXL, XXXL, XXXXL
Surgical Gown	XS, S, M, L, XL, XXL, XXXL, XXXXL
Scrub Suit	XS, S, M, L, XL, XXL, XXXL, XXXXL
Shoe Cover	15x36cm, 16x38cm, 15x41cm, 17x41cm, 17x43cm, 18x40cm, any size can be customized
Caps (Hoods)	(18", 19", 21", 24"), (9g -- 30g), (15mic-50mic), (Single elastic, Double elastic), any size can be customized
Apron	S, M, L, XL, XXL, XXXL, XXXXL, 24"x42", 28"x46", any size can be customized
Bed Sheet	80x180cm, 120x180cm, 120x220cm, 120x240cm, any size can be customized

This annex is only valid if attached to the report mentioned above.



Annex to Report (No. 02995)

Wuhan Aimmax Trade Co., Ltd.

Product Name	Type
Dental Bibs	33x45cm, 40x45cm, any size can be customized
Underpad	60x60cm, 60x90cm, any size can be customized
Earphone Cover	6.5cm, 9cm, 11cm, 13cm, any size can be customized
Sleeve	20x40cm, 20x42cm, 20x46cm, 22x46cm, any size can be customized
Panty	M, L, XL, XXL, any size can be customized
Beard Cover	18", 19", 21", 24", any size can be customized
Glove	S, M, L, XL
Non woven Roll	10cm, 15cm, 16cm, 17.5cm, 18.5cm, any size can be customized
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
Bandages	2.5cmx4.5m, 5cmx4.5m, 7.5cmx4.5m, 10cmx4.5m, 15cmx4.5m, any size can be customized
Surgical Pack	20x13.5cm, 16x11cm, 14x10cm, 12x9.3cm, 18x13x7cm, 22x15x7cm, any size can be customized

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