



European
Commission

Verification of Conformity

Applicant: Nanchang Xiangyi Medical Equipment Co.,Ltd.
Address: North Lidu Industry Park, Nanchang City, Jiangxi Province, China.
Product(s): Examination Gloves, Disposable Surgical Bedsheet, Disposable Surgical Package, Delivery Package, Disposable Mask, Disposable Mask Cap, Cotton Pad, Disposable Cap, Gauze Dressing, Disposable Surgical Gown, Disposable Vaginal Syringe, Disposable Vaginal Speculum, Disposable Vaginal Dilator, Disposable Surgical Drape, Surgical Mask, Medical Cotton Swabs, Tongue Depressors, Medical Cotton Ball, Medical Gauze Bandage, Nursing Pad, Infusion Paste, Band Aid, Cervical Smear, Fever Cooling Gel Patch, Patient Transfer Pad, Disposable Electrode Cloth
Type(s): 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 Directive 2007/47/EC).

Standard(s) used for showing compliance with the essential requirements in the specified directive(s):
Standard(s): EN ISO 14971:2012; EN ISO 15223-1:2012; EN 1041:2008;
EN ISO 10993-1:2009AC:2010; EN ISO 10993-5:2009;
EN ISO 10993-10:2013

The review result of the technical files and test report support the self declaration for the devices listed above. 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.

SUNGO Certification Company Limited



Executive Director
Issued: Feb. 20 2017
Cert. No.: EU 069518
Expiration Date: Feb. 19 2022

Annex to Cert. No.: EU 069518

Product Name	Type
Examination Gloves	large, medium, small
Disposable Surgical Bedsheet	Type A, Type B, Type C, Type D, 40*50cm, 50*60cm, 50*70cm, 80*120cm, 80*150cm, 100*200cm, According to customer requirements
Disposable Surgical Drape	50*60cm, According to customer requirements
Disposable Surgical Package	general purpose type
Disposable Surgical Gown	120*120cm, 120*110cm, 120*118cm, 128*118cm, 135*120cm, 140*130cm
Surgical Mask	17*17cm, Model: Type I, Type II
Disposable Mask	A3, A4, A5, B3, B4, B5
Disposable Mask Cap	Mask: A3, A4, A5, B3, B4, B5; Cap: A1, A2
Disposable Cap	Specifications: 64*14mm, 64*15mm, 50*45mm, Model: A1 there is elastic, A2 no elastic
Delivery Package	Universal type
Medical Gauze Bandage	48*3000mm, 48*4000mm, 48*4500mm, 48*5000mm, 48*5500mm, 48*6000mm, 48*8000mm, 48*10000mm, 60*3000mm, 60*4000mm, 60*4500mm, 60*5000mm, 60*5500mm, 60*6000mm, 60*8000mm, 60*10000mm, 80*3000mm, 80*4000mm, 80*4500mm, 80*5000mm, 80*5500mm, 80*6000mm, 80*8000mm, 80*10000mm, 100*3000mm, 100*4000mm, 100*4500mm, 100*5000mm, 100*5500mm, 100*6000mm, 100*8000mm, 100*10000mm, 120*3000mm, 120*4000mm, 120*4500mm, 120*5000mm, 120*5500mm, 120*6000mm, 120*8000mm, 120*10000mm, 150*3000mm, 150*4000mm, 150*4500mm, 150*5000mm, 150*5500mm, 150*6000mm, 150*8000mm, 150*10000mm
Cotton Pad	Type A1, Type A2, Type B1, Type B2, According to customer requirements
Gauze Dressing	5*7*8cm, 6*8*8cm, 8*10*8cm, A1, C1, According to customer requirements
Disposable Vaginal Dilator	large, medium
Disposable Vaginal Speculum	large, medium, small
Disposable Vaginal Syringe	200ml, 50ml, I, II, III, IV, V
Medical Cotton Swabs	8cm, 10cm, 12cm, 15cm, 16cm, 18cm, 20cm, 24cm, 25cm, 28cm, 30cm, 32cm
Medical Cotton Ball	large, medium, small

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Product Name	Type
Infusion Paste	70*35mm, 70*32mm, 70*38mm, 70*40mm, 70*45mm, 80*50mm, 80*38mm, 75*40mm, 75*45mm, 75*50mm
Tongue Depressors	140mm*18mm, 150mm*18mm, 150mm*16mm, 140mm*16mm
Nursing Pad	50*60cm, 60*90cm, A, B, C
Band Aid	According to customer requirements
Cervical Smear	According to customer requirements
Fever Cooling Gel Patch	20cm*9cm, 15cm*7cm, 12cm*8cm, 12cm*5cm, 12.2cm*4.9cm, 12.5cm*5cm, 12.5cm*4.5cm, 11cm*4cm, 11.7cm*4.7cm, 11.6cm*4.8cm, 11cm*5cm
Patient Transfer Pad	200cm*80cm, According to customer requirements
Disposable Electrode Cloth	Φ 1.8cm, Φ 2cm, Φ 2.2cm, 1.6x1.6cm, 1.8x1.8cm, 2.0x2.0cm, 2.2x2.2cm

END OF THE ANNEX

产品名称	型号规格
医用输液贴	70*35mm,70*32mm,70*38mm,70*40mm,70*45mm,80*50mm,80*38mm,75*40mm,75*45mm,75*50mm
压舌板	140mm*18mm,150mm*18mm,150mm*16mm,140mm*16mm
医用护理垫	50*60cm,60*90cm,A,B,C
创可贴	According to customer requirements
刮宫片	According to customer requirements
医用退热贴	20cm*9cm,15cm*7cm,12cm*8cm,12cm*5cm,12.2cm*4.9cm,12.5cm*5cm,12.5cm*4.5cm,11cm*4cm,11.7cm*4.7cm,11.6cm*4.8cm,11cm*5cm
病人转移垫	200cm*80cm, According to customer requirements
一次性使用电极布	Φ 1.8cm, Φ 2cm, Φ 2.2cm,1.6x1.6cm,1.8x1.8cm,2.0x2.0cm,2.2x2.2cm,