



EC Declaration of Conformity

Regarding Medical Device Directive(93/42/EEC)

including Directive 2007/47/EC

Applicant

Name: YANGZHOU VENCH MEDICAL PRODUCTS CO.,LTD

Address: ROOM 2-1401 CHANGJIAN PLAZA, JINGHUACHENG ROAD, HANJIANG DISTRICT, YANGZHOU, CHINA

EC representative:

Name: SUNGO Europe B.V.

Add: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Face Mask, Cap, Isolation Gown, Surgical Gown, Lab Coat, Coverall, Scrub Suit, Shoe Cover, Beard Cover, Sleeve Cover, Boot Cover, Bed Sheet, Bed Cover, Pillow Cover, Gloves, Apron, Medical Gauze, Medical Absorbent Cotton, Absorbent Cotton Roll, Absorbent Cotton Ball, Medical Bandage

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 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

Signature: 石陈云

Date: 2019-10-15



Annex

Product Name	Type
Face Mask	12.5cm*8.5cm,14.5cm*9cm,17.5cm*9.2cm,17.5cm*9.5cm, or as required
Cap	18",19",21",23",24", or as required
Isolation Gown	S, M ,L ,XL, 2XL,3XL,4XL,5XL,6XL, or as required
Surgical Gown	S, M ,L ,XL, 2XL,3XL,4XL,5XL,6XL, or as required
Lab Coat	S, M ,L ,XL, 2XL,3XL,4XL,5XL,6XL, or as required
Coverall	S, M ,L ,XL, 2XL,3XL,4XL,5XL,6XL, or as required
Scrub Suit	S, M ,L ,XL, 2XL,3XL,4XL,5XL,6XL, or as required
Shoe Cover	15*36cm ,15*41cm,17*38cm,17*41cm, or as required
Beard Cover	18",19",21", or as required
Sleeve Cover	22*46cm,20*40cm, or as required
Boot Cover	40*45cm,40*40cm, or as required
Bed Sheet	140*240cm, or as requested
Bed Cover	250*160cm, 220*120cm,180*80cm,60*60cm,or as required
Pillow Cover	48*27cm, or as required
Gloves	XS,M,L,XL, or as required
Apron	69x107cm,70x120cm,71x122cm,81x122cm,80x125cm,80x140cm, 81x144cm, or as required
Medical Gauze	Mesh: 20*10, 19*15, 26*18, 30*20 or as required Size: 2"x2", 3"x3", 4"x4", 4"x8" or as required Types: X-ray/non X-ray
Medical Absorbent Cotton	25g,50g,100g,150g,200g,250g,300g,350g,400g,450g,500g,1000g or as required
Absorbent Cotton Roll	Cotton Yarn: 21s,32s,40s or Mixed Mesh: 12X8,19X15,26X18,30X20 etc or as required
Absorbent Cotton Ball	0.2g/pc,0.3g/pc,0.5g/pc,1g/pc,2g/pc,3g/pc,4g/pc or as required .
Medical Bandage	1.Elastic cotton gauze bandage cotton yarn:21s,32s,40s;mesh:22,20,18,17,13,12 threads etc. 2.100% cotton bandage Width:2.5cm,5cm,7.5cm,10cm,15cm,20cm max Length: 4m, 5m, 10m.or as required

