



## Compliance Report

**Applicant:** HEFEI MLUSH SANITARY PRODUCTS CO., LTD  
**Address:** WEST WEIXI ROAD, YAOHAI INDUSTRIAL PARK,  
XINZHAN ZONE, HEFEI.  
**Product:** Stop Cock, Isolation Gown, Pull Pants, Urine Bag, Adult Diaper, Baby Diaper, Lab Coat, Protective Gown, Maternity Pad, PE Gloves, PE Apron, PE Sleeves, Dental Mirror, Dental Probe, Dental Tweezers, Retractor, Tongue Depresser, Sharp Container, Oxygen Mask, Nebulizer Mask, Athletic Bandage, Cosmetic Rolls, Cosmetic Pad, Gauze Ball, PP Ball, Surgical Kit, Head Rest Cover, Apron, Patient Drape, PP Gloves  
**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. 02773

Initial Issue Date: 26 Sep 2017

*Tony Chen*

General Manager (Signature)

This report is the property of NQA and should be returned to NQA upon request.



## Annex to Report (No. 02773 )

### HEFEI MLUSH SANITARY PRODUCTS CO.,LTD

Product Name	Type
Stop Cock	10-50cm
Isolation Gown	115*137cm, 120*140cm and according to the order or customer requirements
Pull Pants	46*39cm, 49*41.5cm,53*41 cm and according to the order or customer requirements
Urine Bag	2000ml,1000ml
Adult Diaper	80*65cm, 92*75cm, 99*81 cm and according to the order or customer requirements
Baby Diaper	46*39cm,49*41.5cm,53*41.5cm and according to the order or customer requirements
Lab Coat	105*69cm
Protective Gown	S M L XL XXL, XXXL
Maternity Pad	16.5*38.5cm
PE Gloves	S /M/ L /XL
PE Apron	69*107cm and according to the order or customer requirements
PE Sleeves	20*40cm,22*46cm,22*58cm and according to the order or customer requirements
Dental Mirror	165*6mm, PP/ABS
Dental Probe	170*35mm,2*17CM and according to the order or customer requirements
Dental Tweezers	165*20mm and according to the order or customer requirements
Retractor	120*5.3*18mm,114*42*17mm,130*92*21mm,118*85*17mm, 97*70*15mm,126*57*51mm,100*44*40mm,167*55*24mm, 145*45*20mm and according to the order or customer requirements
Tongue Depresser	18*150mm,and according to the order or customer requirements
Sharp Container	0.7-15L,and according to the order or customer requirements
Oxygen Mask	X/S/,S/,M/,L/,Q/,XL

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## Annex to Report (No. 02773 )

### HEFEI MLUSH SANITARY PRODUCTS CO.,LTD

Product Name	Type
Nebulizer Mask	Adult, Children
Athletic Bandage	2.5cm*5m,3.8cm*5m,5cm*5m,7.5*5m and according to the order or customer requirements
Cosmetic Rolls	12.5*30m
Cosmetic Pad	58mm round,4*4cm,0.4g,0.5g,0.6g and according to the order or customer requirements
Gauze Ball	0.2-2g/pc, and according to the order or customer requirements
PP Ball	3,4,5cm 3:7 30g,40g
Surgical Kit	3pcs/5pcs Dental probe, Dental mirror, Dental tweezers, bib, tray and according to the order or customer requirements
Head Rest Cover	25*33cm,25*25cm,56*75cm and according to the order or customer requirements
Apron	37*60cm,37*70cm,37*57cm and according to the order or customer requirements
Patient Drape	75*75cm,80*1.5m,1m*1.2m and according to the order or customer requirements
PP Gloves	S,M,L,XL

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## Compliance Report

Applicant: HEFEI MLUSH SANITARY PRODUCTS CO.,LTD  
Address: WEST WEIXI ROAD, YAOHAI INDUSTRIAL PARK,  
XINZHAN ZONE,HEFEI  
Product: Sterilization Pouch/Sterilization Reels, Sterilization Crepe  
Paper, Sterilization Tape, Dental Bib, Saliva Ejector, Suction  
Tip, Sani Tip, Cotton Roll, MicroBrush, Plastic Sleeve, Barrier  
Film, Dental Kit, Bed Sheet Roll, Underpad, Face Mask,  
Surgical Gown, Doctor Cap, Gauze Swab, Non-woven  
Sponge, Polish Brush, Disposable Syringe, Dental Needle,  
Cotton Wool, Cotton Ball, Impression Tray, Endo Block,  
Alcohol Swab, Non-woven Fabric Rolls, Shoe Cover,  
Bandage, Surgical Tape, Latex Gloves, Vinyl Gloves, Nitrile  
Gloves, Smooth Paper, Autoclave Indicator Tape, Urine Bottle,  
Plastic Trays, Plastic Tubes, Urine Cup, Pipet Tip,  
Microscope Slide  
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. 02772

Initial Issue Date: 26 Sep 2017

*Tony Chen*

General Manager (Signature)

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## Annex to Report (No. 02772 )

### HEFEI MLUSH SANITARY PRODUCTS CO.,LTD

Product Name	Type
Sterilization Pouch/ Sterilization Reels	60*100mm,60*130mm,70*260mm,80*160mm, 90*165mm,90*230mm,90*260mm,110*280mm, 135*260, 135*280, 195*330, 195*360, 255*380, 300*395, 300*430 and according to the order or customer requirements
Sterilization Crepe Paper	300mmx300mm,400mmx400mm,500mmx500mm, 600mmx600mm,900mmx900mm,1000mmx1000mm and according to the order or customer requirements
Sterilization Tape	12mm x 50m, 19mm x 50m, 25mm x 50m and according to the order or customer requirements
Dental Bib	33x45cm and according to the order or customer requirements
Saliva Ejector	15cm
Suction Tip	Vented, Non-Vented
Sani Tip	Plastic inner core, metal inner core
Cotton Roll	8*38mm, 10*38mm, 12*38mm and according to the order or customer requirements
MicroBrush	S/M/L
Plastic Sleeve	10*11", 29*80", 1.8*17.7"
Barrier Film	4" x 6" 1200pcs
Dental Kit	3 in 1, 5 in 1, 7 in 1, 8 in 1, 12 in 1 and according to the order or customer requirements
Bed Sheet Roll	width 40cm-100cm*length 40m-200m/roll and according to the order or customer requirements
Underpad	50cm*50cm,60*60,60cm*80cm,60cm*90cm ,80cm*120cm, 80cm*150cm and according to the order or customer requirements
Face Mask	17.5 x9.5cm
Surgical Gown	S/M/L/XL/XXL and according to the order or customer requirements

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## Annex to Report (No. 02772 )

### HEFEI MLUSH SANITARY PRODUCTS CO.,LTD

Product Name	Type
Doctor Cap	18" 19" 20" 21" 24"
Gauze Swab	5x5cm, 7.5x7.5cm, 10x10cm and according to the order or customer requirements
Non-woven Sponge	5x5cm, 7.5x7.5cm, 10x10cm and according to the order or customer requirements
Polish Brush	Large, medium, trumpet
Disposable Syringe	1ml, 2.5ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml and according to the order or customer requirements
Dental Needle	25G, 27G, or 30G and according to the order or customer requirements
Cotton Wool	1kg, 2kg, 5kg and according to the order or customer requirements
Cotton Ball	S,M,L
Impression Tray	S,M,L
Endo Block	L100MM*D24MM*H32MM
Alcohol Swab	3x6.5cm, 3x3cm, 4x8cm, 9x10cm
Non-woven Fabric Rolls	50*100cm, 60*100cm and according to the order or customer requirements
Shoe Cover	S,M,L
Bandage	6000mm×48mm,6000mm×60mm,6000mm×80mm, 6000mm×100mm,5000mm×60mm,5000mm×80mm, and according to the order or customer requirements
Surgical Tape	12mmx50m, 19mmx50m, 25mmx50m
Latex Gloves	XS,S,M,L,XL
Vinyl Gloves	XS,S,M,L,XL
Nitrile Gloves	XS,S,M,L,XL
Smooth Paper	18"*225",21"*225"
Autoclave Indicator Tape	12.5mm*50m,19mm*50m,19mm*55m

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**Annex to Report (No. 02772 )**

**HEFEI MLUSH SANITARY PRODUCTS CO.,LTD**

Product Name	Type
Urine Bottle	length between 25cm and 35cm,width between 10cm and 15cm and according to the order or customer requirements
Plastic Trays	length between 15cm and 40cm, width between 10cm and 30cm.
Plastic Tubes	1ml,2ml,3ml,5ml
Urine Cup	40ml,60ml,120ml
Pipet Tip	10ul 96wells and according to the order or customer requirements
Microscope Slide	25.4*76.2cm,25*75cm,26*76cm,90°,45° and according to the order or customer requirements

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