



## 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<br>and according to the order or customer requirements  |
| Pull Pants       | 46*39cm, 49*41.5cm,53*41 cm<br>and according to the order or customer requirements   |
| Urine Bag        | 2000ml,1000ml  |
| Adult Diaper     | 80*65cm, 92*75cm, 99*81 cm<br>and according to the order or customer requirements  |
| Baby Diaper      | 46*39cm,49*41.5cm,53*41.5cm<br>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<br>and according to the order or customer requirements  |
| PE Sleeves       | 20*40cm,22*46cm,22*58cm<br>and according to the order or customer requirements   |
| Dental Mirror    | 165*6mm, PP/ABS  |
| Dental Probe     | 170*35mm,2*17CM<br>and according to the order or customer requirements   |
| Dental Tweezers  | 165*20mm<br>and according to the order or customer requirements  |
| Retractor        | 120*5.3*18mm,114*42*17mm,130*92*21mm,118*85*17mm,<br>97*70*15mm,126*57*51mm,100*44*40mm,167*55*24mm,<br>145*45*20mm<br>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<br>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<br>and according to the order or customer requirements                                   |
| Gauze Ball       | 0.2-2g/pc,<br>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<br>and according to the order or customer requirements |
| Head Rest Cover  | 25*33cm,25*25cm,56*75cm<br>and according to the order or customer requirements   |
| Apron            | 37*60cm,37*70cm,37*57cm<br>and according to the order or customer requirements   |
| Patient Drape    | 75*75cm,80*1.5m,1m*1.2m<br>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.

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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/<br>Sterilization Reels | 60*100mm,60*130mm,70*260mm,80*160mm,<br>90*165mm,90*230mm,90*260mm,110*280mm,<br>135*260, 135*280, 195*330, 195*360, 255*380, 300*395,<br>300*430<br>and according to the order or customer requirements |
| Sterilization Crepe Paper                   | 300mmx300mm,400mmx400mm,500mmx500mm,<br>600mmx600mm,900mmx900mm,1000mmx1000mm<br>and according to the order or customer requirements   |
| Sterilization Tape                          | 12mm x 50m, 19mm x 50m, 25mm x 50m<br>and according to the order or customer requirements  |
| Dental Bib                                  | 33x45cm<br>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<br>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<br>and according to the order or customer requirements   |
| Bed Sheet Roll                              | width 40cm-100cm*length 40m-200m/roll<br>and according to the order or customer requirements   |
| Underpad                                    | 50cm*50cm,60*60,60cm*80cm,60cm*90cm ,80cm*120cm,<br>80cm*150cm<br>and according to the order or customer requirements  |
| Face Mask                                   | 17.5 x9.5cm  |
| Surgical Gown                               | S/M/L/XL/XXL<br>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<br>and according to the order or customer requirements   |
| Non-woven Sponge         | 5x5cm, 7.5x7.5cm, 10x10cm<br>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<br>and according to the order or customer requirements                            |
| Dental Needle            | 25G, 27G, or 30G<br>and according to the order or customer requirements  |
| Cotton Wool              | 1kg, 2kg, 5kg<br>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<br>and according to the order or customer requirements  |
| Shoe Cover               | S,M,L  |
| Bandage                  | 6000mm×48mm,6000mm×60mm,6000mm×80mm,<br>6000mm×100mm,5000mm×60mm,5000mm×80mm,<br>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<br>and according to the order or customer requirements  |
| Microscope Slide | 25.4*76.2cm,25*75cm,26*76cm,90°,45°<br>and according to the order or customer requirements                   |

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