European Commission

Verification of Conformity

Applicant:	WELLMED DENTAL MEDICAL SUPPLY CO., LTD
Address:	F116,4/F, Hehe Mansion,No.68 Xin'an 2nd Road, Baoan Dist., Shenzhen, China
Product(s):	DISPOSABLE DENTAL PARTS: Face Masks, Face mask with shield, Lab coats, Spa suites, Tie Back Protective Gowns, Isolation Gown, Shoes covers, Caps, Facial masks, Facial towels, Gloves, Underwear, Bed sheets, Non-Woven Sponges, Cotton pads, Under pads, Pillowcase; Cotton roll, Cotton tipped applicators, Gauze Sponges, Cotton Filled Sponges; Disposable Evacuators, Tips-vented, Saliva Ejectors, standard Tip, Disposable Surgical Tips, Disposable Impression Trays, Bite Registration Tray, Barrier Film, Syringe Sleeves, Handpiece Sleeves, Light Handle Covers, X-Ray Covers, Tray Sleeves, Half Chair Cover, Headrest Cover Sleeve, Sensor Cover, Digital X-Ray Sensor Protector, Full Chair Cover, Intral Oral Camera Sleeves, Air/Water Syringe Tips, Dental Bib Clip, Plastic Cups, HP Impression Materials Mixing Tips, Plastic Intra-Oral Tips, Micro Applicators, Denture Box, Cheek Retractors, Cotton Roll Dispenser, Fluoride Tray, Prophy Angle, CPE Apron,individually packed Spatulas, Mixing Bowls, DAPPENS DISH, BUR HOLDER, Prophy Brush; Dental Bibs, Dental Apron with pocket, Self Sealing Sterilization Pouches/Reels; Dental Mirror, Dental Kits, Dental Probe, Dental Tweezers
Type(s):	NA
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 10993-1:2010; EN ISO 10993-5:2009; EN ISO 10993-10:2010; EN1639:2009

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

CE

Sungo global

Digitally signed by Jighili Tatiana
Date: 2019.01.03 12:51:19 EET
Reason: MoldSign Signature
Location: Moldova

Executive Director
Issued: Aug. 16 2016
Cert. No.: EU 056518
Expiration Date: Aug. 15 2021

European Commission

Verification of Conformity

Applicant:	WELLMED DENTAL MEDICAL SUPPLY CO., LTD
Address:	F116,4/F, Hehe Mansion,No.68 Xin'an 2nd Road, Baoan Dist., Shenzhen, China
Product(s):	Face Masks, Face mask with shield, Lab coats, Spa suites, Tie Back Protective Gowns, Isolation Gown, Shoes covers, Caps, Facial masks, Facial towels, Gloves, Underwear, Bed sheets, Non-Woven Sponges, Cotton pads, Under pads, Pillowcase
Type(s):	NA
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 10993-1:2010; EN ISO 10993-5:2009; EN ISO 10993-10:2010

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.

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Executive Director
Issued: Aug. 16 2016
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Expiration Date: Aug. 15 2021

European Commission

Verification of Conformity

Applicant:	WELLMED DENTAL MEDICAL SUPPLY CO., LTD
Address:	F116,4/F, Hehe Mansion,No.68 Xin'an 2nd Road, Baoan Dist., Shenzhen, China
Product(s):	Cotton roll, Cotton tipped applicators, Gauze Sponges, Cotton Filled Sponges
Type(s):	NA
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 10993-1:2010;
EN ISO 10993-5:2009; EN ISO 10993-10:2010

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.

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Executive Director
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Cert. No.: EU 056518-2
Expiration Date: Aug. 15 2021

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Add: 4th Floor, No.1500 Central Avenue, Shanghai 200122, P.R.China

European Commission

Verification of Conformity

Applicant:	WELLMED DENTAL MEDICAL SUPPLY CO., LTD
Address:	F116,4/F, Hehe Mansion,No.68 Xin'an 2nd Road, Baoan Dist., Shenzhen, China
Product(s):	Disposable Evacuators, Tips-vented, Saliva Ejectors, standard Tip, Disposable Surgical Tips, Disposable Impression Trays, Bite Registration Tray, Barrier Film, Syringe Sleeves, Handpiece Sleeves, Light Handle Covers, X-Ray Covers, Tray Sleeves, Half Chair Cover, Headrest Cover Sleeve, Sensor Cover, Digital X-Ray Sensor Protector, Full Chair Cover, Intral Oral Camera Sleeves, Air/Water Syringe Tips, Dental Bib Clip, Plastic Cups, HP Impression Materials Mixing Tips, Plastic Intra-Oral Tips, Micro Applicators, Denture Box, Cheek Retractors, Cotton Roll Dispenser, Fluoride Tray, Prophy Angle, CPE Apron,individually packed Spatulas, Mixing Bowls, DAPPENS DISH, BUR HOLDER, Prophy Brush
Type(s):	NA
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; EN1639:2009

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

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European Commission

Verification of Conformity

Applicant:	WELLMED DENTAL MEDICAL SUPPLY CO., LTD
Address:	F116,4/F, Hehe Mansion,No.68 Xin'an 2nd Road, Baoan Dist., Shenzhen, China
Product(s):	Dental Bibs, Dental Apron with pocket, Self Sealing Sterilization Pouches/Reels
Type(s):	NA
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 10993-1:2010;
EN ISO 10993-5:2009; EN ISO 10993-10:2010

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

CE Sungo global service

Executive Director
Issued: Aug. 16 2016
Cert. No.: EU 056518-4
Expiration Date: Aug. 15 2021

European Commission

Verification of Conformity

Applicant:	WELLMED DENTAL MEDICAL SUPPLY CO., LTD
Address:	F116,4/F, Hehe Mansion,No.68 Xin'an 2nd Road, Baoan Dist., Shenzhen, China
Product(s):	Dental Mirror, Dental Kits, Dental Probe, Dental Tweezers
Type(s):	NA
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; EN1639:2009

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

CE Sungo global service

Executive Director
Issued: Aug. 16 2016
Cert. No.: EU 056518-5
Expiration Date: Aug. 15 2021

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