



HEALTHCARE SUPPLIES CATALOGUE



WWW.VIRTUS.AE
SALES@VIRTUS.AE

INTRODUCTION

Virtus is a healthcare Trade Supply chain partner of products including specialised drug supplies. Through our strategic offices in London (UK), Dubai (UAE), Mumbai (INDIA), Portugal and Shanghai(China), we are capable of handling worldwide distribution and sales 24/7 when required.

Virtus understands client demands and capacity enabling timely and strong inventory planning management to support customer needs. With over 200 years of combined global distribution and logistics experience we have been able to build a strong track record of delivering over 22 million Medical unit supplies as of date and growing. Virtus offers partial or full loads under its own brand or OEM as per customer requirements.

Contact Virtus on email sales@virtus.ae for further information.

WWW.VIRTUS.AE



Personal Protective Solutions

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Hygiene Solutions

1) Extra Large Antibacterial Hand Sanitizer _____ 74

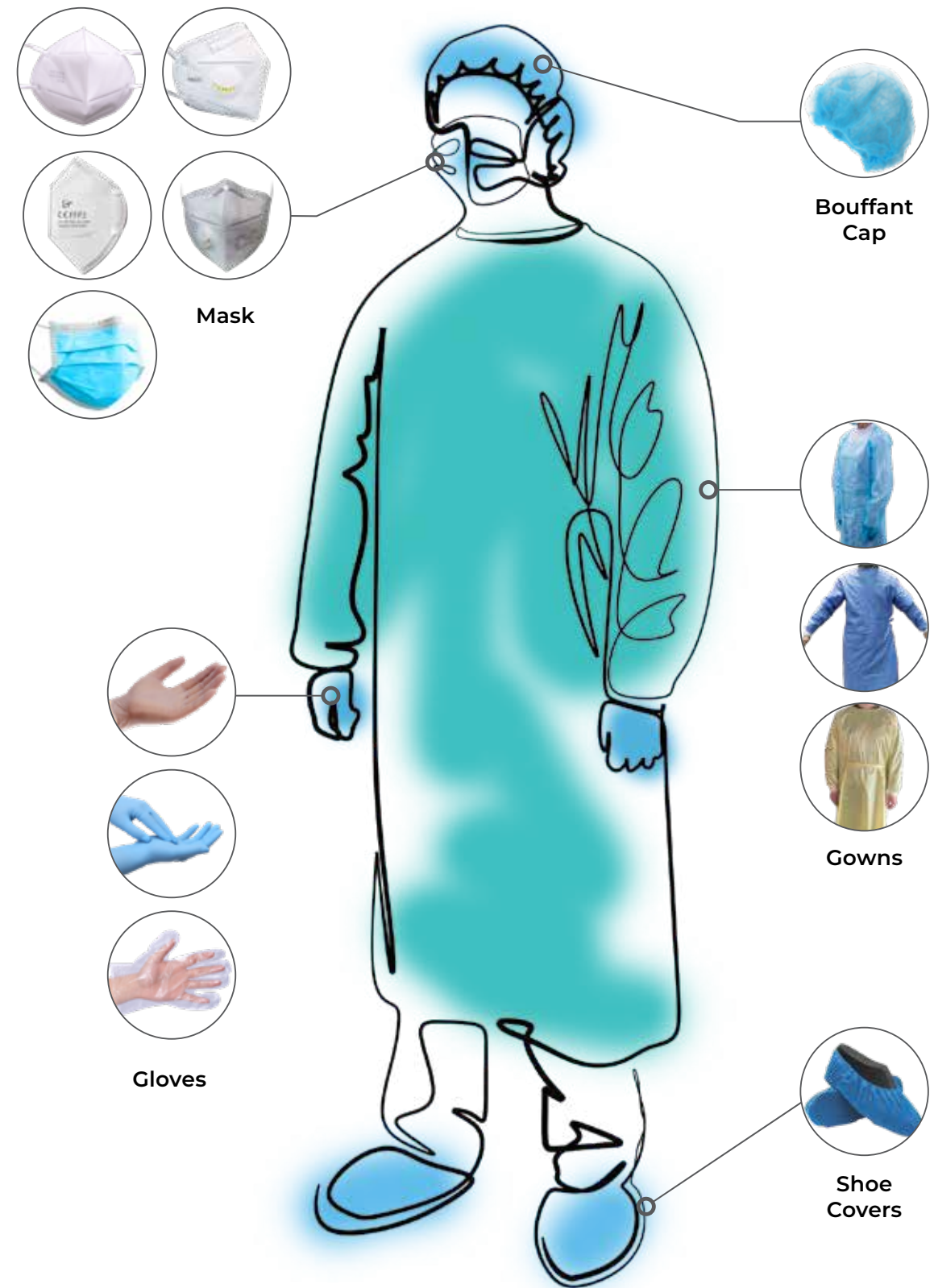
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Disclaimer: Box designs and logos of Virtus / OEM might vary based on the country of manufacture due to customs permission limitations of using the medical word in certain jurisdiction. Virtus has the right to change its propriety box design for enhancing and improving its product packaging from time to time. Packaging displayed above may or may not be the exact design of the current box design in place depending on the time of your order.

PERSONAL PROTECTIVE SOLUTIONS



LEVEL 2 - 3 PLY PROTECTIVE MASK



	Level 2 - 3 Ply Protective Mask				
 SKU#	MAS3P001				
 Material	Non sterile & non-woven, latex free, & hypoallergenic.				
 Make	Machine Made				
 Country of Manufacture	Made in China, India  				
 Mask Size	17 x 9.5				
 Color					
 Size	Universal				
 Characteristics	3 Ply EarLoop Face Mask Adjustable nose clamp for a perfect 3D fit. Resist harmful substances, 98% filtration capacity.				
 Places of Use	Clinics, healthcare facilities, dental clinics, pre-cleanroom gowning area, laboratories, homes, food processing industries, factories, educational institutions, parks & recreational tourism, densely populated areas and frontline.				
 Protection	Conformity & Quality Standards Check				
	Approved				
	Testing Levels Check	EN 14683	ISO 22609	EN ISO 11737-1	ASTM
	Approved				




























	Level 2 - 3 Ply Protective Mask
<div>Box Size</div>	19.8 x 11 x 8.8
<div>Carton Size</div>	57.2 x 40.5 x 38
<div>Weight of Product</div>	3 g
<div>Quantity per Carton</div>	50 pcs x 40 box = 2,000 masks
<div>Net Weight</div>	9 kgs
<div>Gross Weight</div>	10 kgs
<div>Cartons per Pallet</div>	25 to 30 ctns = 50,000 to 60,000 pcs total qty

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KN95
& EN149



























	Headloop KN95-GB2626-2006				
 SKU#	MASKN001				
 Material	PP non-woven fabric, electrostatic filter material, melt-blown fabric.				
 Make	Machine Made				
 Country of Manufacture	Made in China				
 Mask Size	15.5 x 10.7				
 Color					
 Size	Universal				
 Characteristics	The Model Headloop KN95 GB2626-2006 is a light weight, disposable particulate no-valve respirator constructed from 4 layers of material, it's foldable design, contour fit with soft lining and headloop allows your staff wear to this mask all day. According to the standard GB2626-2006, the material in the KN95 face mask is designed for filtration efficiency of at least 95% of particulate matter >0.3 microns.				
 Places of Use	Clinics, healthcare facilities, dental clinics, pre-cleanroom gowning area, laboratories, homes, food processing industries, factories, educational institutions, parks & recreational tourism, densely populated areas and frontline.				
 Protection	Conformity & Quality Standards Check				
	Approved				
	Testing Levels Check	EN 14683	ISO 22609	EN ISO 11737-1	ASTM
	Approved				










	Headloop KN95-GB2626-2006
 Box Size	15.5 x 8.5 x 18.0
 Carton Size	48 x 44 x 38.5
 Weight of Product	5.5 g
 Quantity per Carton	20 pcs x 30 box = 600 masks
 Net Weight	2.8 kgs
 Gross Weight	6 kgs
 Cartons per Pallet	30 ctns = 18,000 pcs total qty

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
















	Headloop KN95-GB2626-2006 with Valve				
 SKU#	MASKN002				
 Material	PP non-woven fabric, electrostatic filter material, melt-blown fabric.				
 Make	Machine Made				
 Country of Manufacture	Made in China 				
 Mask Size	15.5 x 10.7				
 Color					
 Size	Universal				
 Characteristics	The Model Headloop KN95 GB2626-2006 with Valve Respirator is a light weight disposable particulate respirator. Constructed from 4 layers of material it's foldable design contour fit with soft lining and headloop allows your staff to wear this mask all day. According to the standard GB2626-2006, the material in the KN95 face mask is designed for filtration efficiency of at least 95% of particulate matter >0.3 microns.				
 Places of Use	Clinics, healthcare facilities, dental clinics, pre-cleanroom gowning area, laboratories, homes, food processing industries, factories, educational institutions, parks & recreational tourism, densely populated areas and frontline.				
 Protection	Conformity & Quality Standards Check				
	Approved				
	Testing Levels Check	EN 14683	ISO 22609	EN ISO 11737-1	ASTM
	Approved				










	Headloop KN95-GB2626-2006 with Valve
 Box Size	15.5 x 8.5 x 18.0
 Carton Size	48 x 44 x 38.5
 Weight of Product	8.5 g
 Quantity per Carton	10 pcs x 30 box = 300 masks
 Net Weight	2.8 kgs
 Gross Weight	4 kgs
 Cartons per Pallet	30 ctns = 9,000 pcs total qty

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
















	Headloop EN149-FFP2				
 SKU#	MASKN003				
 Material	PP non-woven fabric, electrostatic filter material, melt-blown fabric.				
 Make	Machine Made				
 Country of Manufacture	Made in China				
 Mask Size	15.5 x 10.7				
 Color					
 Size	Universal				
 Characteristics	Headloop particulate surgical respirators EN149-FFP2 are commonly used in healthcare settings in Europe and are a subset of the N95 face piece respirator (FFP2). Recommended by World Health Organisation they help reduce the spread of viruses.				
 Places of Use	Clinics, healthcare facilities, dental clinics, pre-cleanroom gowning area, laboratories, homes, food processing industries, factories, educational institutions, parks & recreational tourism, densely populated areas and frontline.				
 Protection	Conformity & Quality Standards Check				
	Approved				
	Testing Levels Check	EN 14683	ISO 22609	EN ISO 11737-1	ASTM
	Approved				










	Headloop EN149-FFP2
 Box Size	15.5 x 8.5 x 18.0
 Carton Size	48 x 44 x 38.5
 Weight of Product	6.28 g
 Quantity per Carton	20 pcs x 30 box = 600 masks
 Net Weight	3 kgs
 Gross Weight	7 kgs
 Cartons per Pallet	30 ctns = 18,000 pcs total qty

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	Headloop EN149-FFP2 with Valve				
 SKU#	MASKN004				
 Material	PP non-woven fabric, electrostatic filter material, melt-blown fabric.				
 Make	Machine Made				
 Country of Manufacture	Made in China				
 Mask Size	15.5 x 10.7				
 Color					
 Size	Universal				
 Characteristics	Headloop particulate surgical respirators EN149-FFP2 with Valve are commonly used in healthcare settings in Europe and are a subset of N95s face piece respirators (FFP2). Recommended by World Health Organisation they help reduce the spread of viruses.				
 Places of Use	Clinics, healthcare facilities, dental clinics, pre-cleanroom gowning area, laboratories, homes, food processing industries, factories, educational institutions, parks & recreational tourism, densely populated areas and frontline.				
 Protection	Conformity & Quality Standards Check				
	Approved				
	Testing Levels Check	EN 14683	ISO 22609	EN ISO 11737-1	ASTM
	Approved				










	Headloop EN149-FFP2 with Valve
 Box Size	15.5 x 8.5 x 18.0
 Carton Size	48 x 44 x 38.5
 Weight of Product	9.28 g
 Quantity per Carton	10 pcs x 30 box = 300 masks
 Net Weight	6 kgs
 Gross Weight	5 kgs
 Cartons per Pallet	30 ctns = 9,000 pcs total qty

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DESIGNER MASK



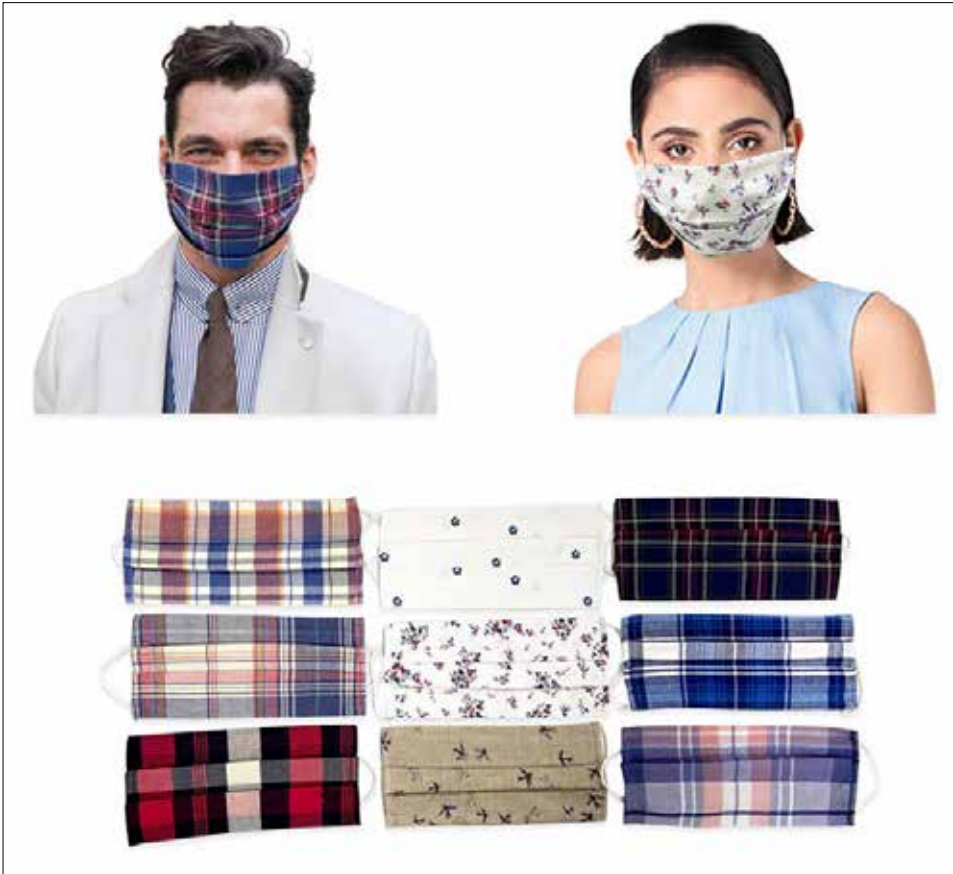
	Designer Masks
 SKU#	DESCLO1
 Material	100% cotton
 Make	Machine Made
 Country of Manufacture	Made in China 
 Characteristics	Reusable non medical mask
 Places of Use	General





	Designer Masks
 Carton Size	60 x 35 x 15
 Quantity per Carton	300 pcs
 Net Weight	3.75 kgs
 Gross Weight	4.5 kgs
 Cartons per Pallet	144 ctns

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CERTIFICATIONS FOR MASKS



FDA Registration Confirmation

This is to confirm that, as the US Agent, we have completed the registration activation confirmation for the **FDA Establishment Registration and Device Listing** with the US Food & Drug Administration for the Fiscal Year 2020 of

ZHANGJIAGANG ANDA PLASTIC PRODUCTS CO., LTD
No.166 Jingu, Phoenix Town Zhangjiagang, Jiangsu, 215614, CHINA

The facility registration and device listing information:

Owner/Operator Number: 10072061		
Device Listing No.	Product Code	Product Name(s)
D397015	QKR	Face Mask
D397017	LYU	Disposable Glove, PE Glove, PE Apron
D397018	FYE	PE Gown, CPE Gown, Plastic Gown

SUNGO Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this attestation until the end of the calendar year stated above, unless said registration is terminated after issuance of this attestation. SUNGO Technical Service Inc. makes no other representations or warranties, nor does this attestation make any representations or warranties to any person or entity other than the named attestation holder, for whose sole benefit it is issued. This attestation does not denote endorsement or approval of the attestation-holder's device or establishment by the U.S. Food and Drug Administration. SUNGO Technical Service Inc. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue an attestation of registration, nor does the U.S. Food and Drug Administration recognize an attestation of registration, SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.

Reference Number: 2007US303518
Issue date: Apr.26, 2020

SUNGO Technical Service Inc.
6050 W EASTWOOD AVE APT 201
CHICAGO, ILLINOIS 60630, USA
sungo.group@yahoo.com





EC REP CERTIFICATE



CMC MEDICAL DEVICES & DRUGS SL

NO. CMC/CE/2020/27042020.2

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

Zhangjiagang Anda Plastic Products Co.,Ltd.

No.166 Jingu Road, Phoenix Town, Zhangjiagang, Suzhou City, Jiangsu Province ,China.

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.

The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/609/2020**





Authorized Signatory
CMC Medical Devices & Drugs SL


Issued on: 27/04/2020

Valid until: 26/04/2021

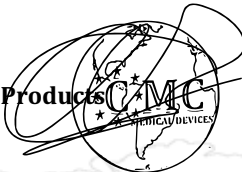
www.cmcmedicaldevices.com




EC REP CERTIFICATE




ANNEX I Medical Device Products




Disposable Medical Face Mask





www.cmcmedicaldevices.com





Compliance Report

Applicant: Zhangjiagang Anda Plastic Products Co., Ltd.
Address: No.166 Jingu Road, Phoenix Town, Zhangjiagang City, Jiangsu Province, China.

Product: HD/LDPE Glove, CPE Glove, TPE Glove, EVA Glove, PE Sleeve, PE Shoe Cover, PE Apron, Surgical Gown
Type: XS, S, M, L, XL, XXL

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. 02520
Initial Issue Date: 17 May 2016


General Manager (Signature)

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





统一社会信用代码: 913101207836407081
证照编号: 26000000202003110354

名称: 上海德宝医疗器械有限公司
类型: 有限责任公司(自然人投资或控股)
法定代表人: 钱德宝
经营范围: 许可项目: 第二类医疗器械生产, 医用口罩生产, (依法须经批准的项目, 经相关部门批准后方可开展经营活动, 具体经营项目以相关部门批准文件或许可证件为准) 一般项目: 第一类医疗器械销售; 第二类医疗器械销售; 第一类医疗器械生产; 医用口罩生产; 医护人员防护用品批发; 日用口罩(非医用)生产; 日用口罩(非医用)销售; 劳保用品批发; 卫生用品和一次性使用医疗用品销售; 文具用品批发; 卫生用品批发; 服装服饰批发; 针纺织品批发; 机械设备租赁; 医疗设备租赁; 信息咨询服务(不含许可类信息咨询服务); 数据处理和存储服务; 广告设计、制作、代理; 酒店管理; 货物进出口。(除依法须经批准的项目外, 凭营业执照依法自主开展经营活动)

注册资本: 人民币8000.0000万元整
成立日期: 2005年12月19日
营业期限: 2005年12月19日至2035年12月18日
住所: 上海市奉贤区华国路913号第四幢

登记机关: 奉贤区市场监督管理局
2020年03月11日

国家企业信用信息公示系统网址: <http://www.gsxt.gov.cn>
市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。
国家市场监督管理总局监制

出口资质:

海关进出口货物收发货人备案回执

企业名称	上海德宝医疗器械有限公司
统一社会信用代码	91310120783640708H
海关备案日期	2020-03-18
海关编码	3117960APJ
检验检测设备号	3170200342
有效期	长期

自然人、法人或者其他法人组织可通过“中国海关企业进出口信用信息公示平台”(<http://credit.customs.gov.cn>) 或者“互联网+海关”(<http://online.customs.gov.cn>) 查询海关公示的企业信息。

对外贸易经营者备案登记表

上海德道医疗设备有限公司 Shanghai dedao medical equipment co., LTD	
注册地址/住所 上海市浦东新区川沙新镇川沙路400号	经营范围/业务 医疗器械销售
法定代表人 王强	联系电话 13916999999
电子邮箱 wangqiang@dedao.com	传真 021-31111111
邮政编码 201200	网址 www.dedao.com
开户银行及账号 招商银行上海分行	开户名称 上海德道医疗设备有限公司

Source: Author's calculations based on data from the U.S. Census Bureau.

合資及外商內資企業	註冊資本	非控股股份	91122018704295611
主營業務	預付方式	(原委用)	
核准辦理工商登記的範圍 (填或) 企業或個體工商戶 (簡括經營者) 是請填明以下內容 是否投資於個人、 十個工商業內人姓名 是否開戶、平口開戶 是否設有分公司 是否進口			

请贵部确认该图符合设计条件，并由监理单位代表人填写工程验收意见签字。盖章



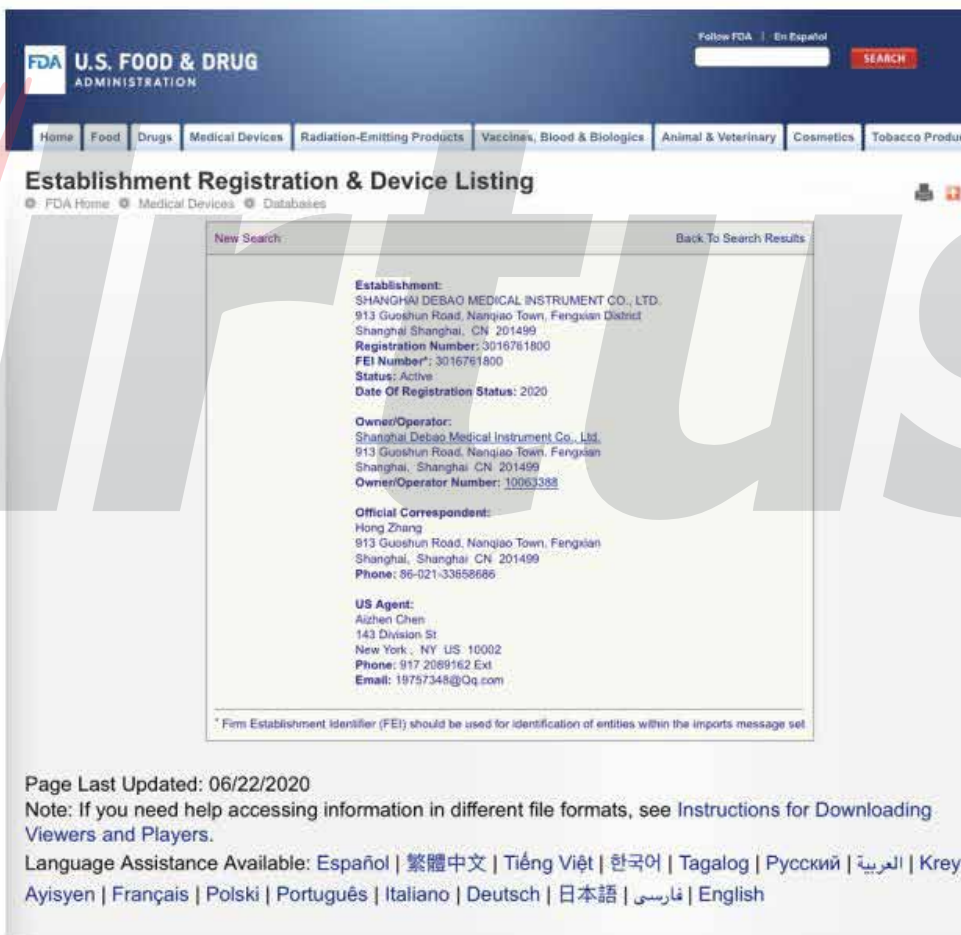
2020 年 11 月 15 日



Page Last Updated: 06/22/2020

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Avisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English



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001568520062455



第二类医疗器械经营备案凭证

备案号：沪奉食药监械经营备 20200345 号

企业名称	上海德宝医疗器械有限公司
法定代表人	钱德宝
企业负责人	钱德宝
经营方式	批发
住 所	上海市奉贤区奉浦国顺路 913 号第四幢
经营场所	上海市奉贤区奉浦国顺路 913 号第四幢
库房地址	上海市奉贤区奉浦国顺路 913 号第四幢
经营范围	第二类医疗器械（不含体外诊断试剂）***

备案部门：上海市奉贤区市场监督管理局

（公章）
备案日期：2020 年 6 月 2 日

依据上海市药品监督管理局《关于实施医疗器械经营许可证及经营备案凭证合并办理的通知》（沪药监械管〔2019〕92 号），企业许可与备案的实时信息以上海市药监局政务网站或原发证部门政务网站公示信息为准。

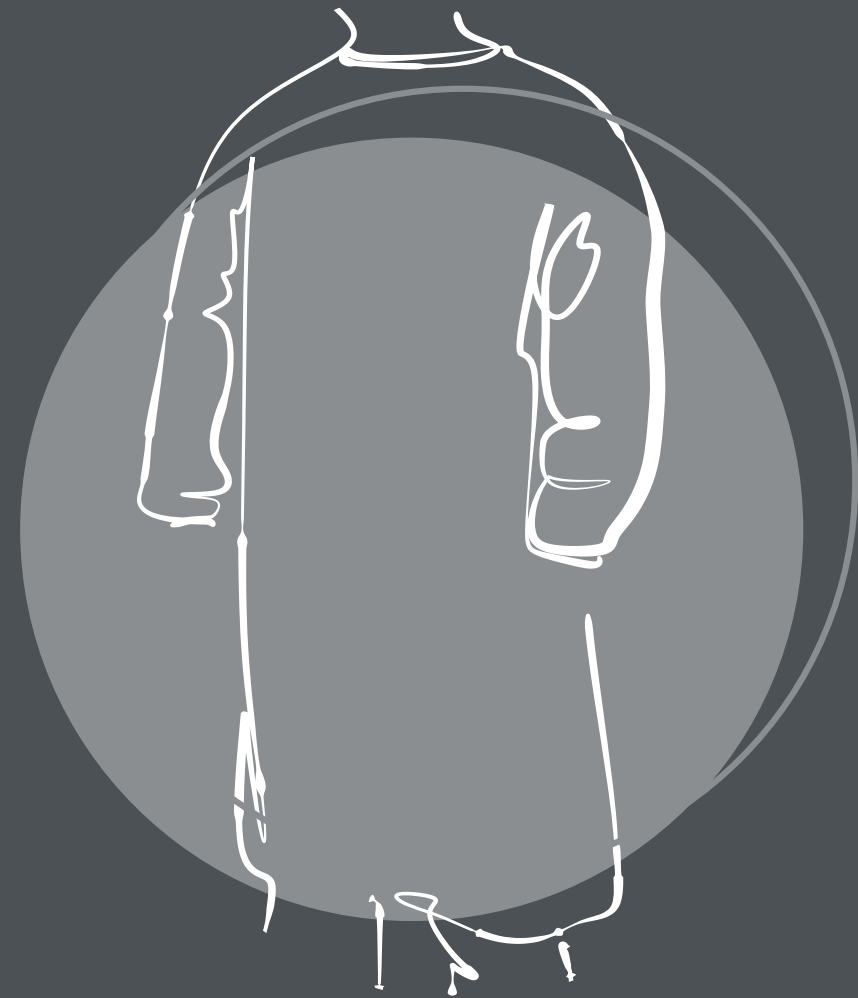


ISO9001证书：






























国家企业信用信息公示系统网址: <http://www.gsxt.gov.cn> 市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。 国家市场监督管理总局监制
















GOWNS



	PE (Plastic/Polyethylene), SMS, Fabric Gowns							
<div></div> <div>Material</div>	Non sterile, non-woven PE laminated & lightweight SMS material.							
<div></div> <div>Description</div>	Level 1: Minimal Risk To be used for basic care, standard isolation, cover gown for visitors or in a standard medical unit.				Level 2: Low Risk AAMI Level 2 approved. To be used for drawing blood, suturing, Intensive Care Unit (ICU) or a pathology lab.			
	Level 3: High Risk AAMI Level 3 approved. If the product passes the AATCC 42 and AATCC 127 in all applicable areas, then it qualifies as an AAMI Level 3 gown.				Level 4: High Risk AAMI Level 3 approved. If the product passes the ASTM F1671 in all applicable areas, then it qualifies as an AAMI Level 4 gown.			
<div></div> <div>Country of Manufacture</div>	Made in China 							
<div></div> <div>Color</div>								
<div></div> <div>Size</div>	S, M, L, XL							
<div></div> <div>Characteristics</div>	Full sleeve gown with secure neck ties to ensure proper glove donning. Full coverage with overlapping panels. Strong sealed seams are designed to withstand even rough treatment, offering 360° total protection. Resists harmful substances, protects against dirt, moisture and fluid under light to moderate pressure conditions.							
<div></div> <div>Places of Use</div>	Clinics, healthcare facilities, dental clinics, pre-cleanroom gowning area, laboratories, homes, food processing industries, factories, educational institutions, parks & recreational tourism, densely populated areas and frontline.							
<div></div> <div>Protection</div>	Conformity & Quality Standards Check							
	Approved							
	Testing Levels Check	EN20811	SMS AAMI LEVEL 2	AAMI LEVEL 3	AAMI LEVEL 4	AATCC 127 & AATCC 42	ANSI/ AAMI PB70	ASTM F1671/ F1671M
	Approved							



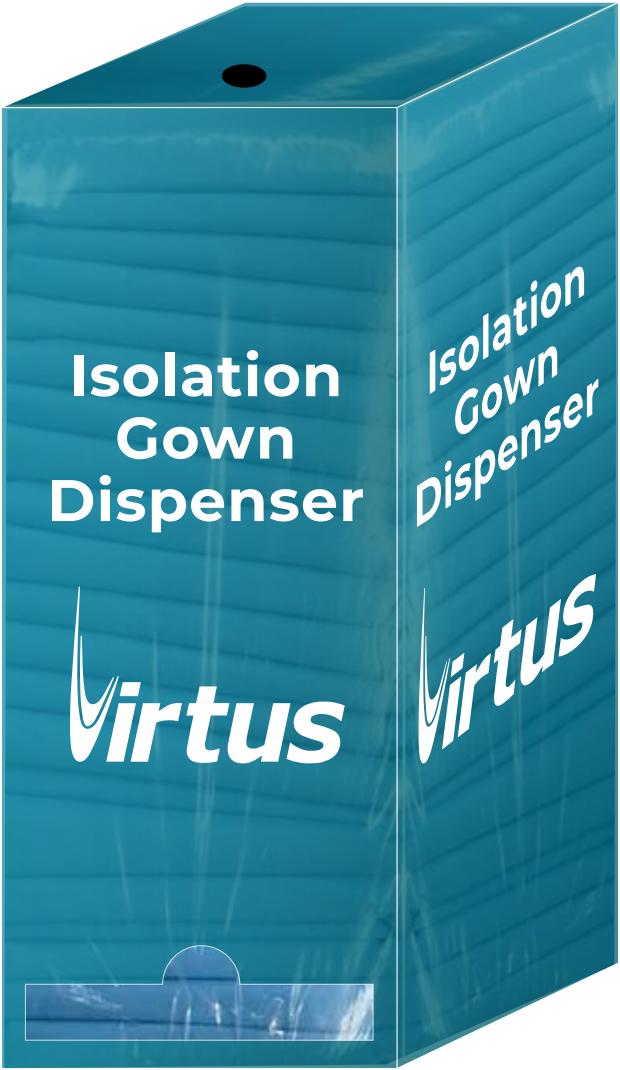
		Level 1 - 3 Isolation Gown	Level 4 Isolation Gown	Level 2 - 3 Isolation Fabric Gown
SKU#		Level 1 (GWPL101) Level 2 (GWPL202) Level 3 (GWPL303)	Level 4 (GWPL404)	Level 2 (GWFL202) Level 3 (GWFL303)
Size		S, M, L, XL	S, M, L, XL	S, M, L, XL
Color				
GSM		18 g - 60 g	60 g - 80 g	40 g - 60 g
Length of Gown		115 - 130 cms	115 - 130 cms	105 - 115 cms
Gowns per Carton		100 pcs	100 pcs	60 pcs
Carton Size		35 x 21 x 38	40 x 22 x 45	60 x 40 x 40
Net Weight		5.0 kgs	7.5 kgs	9 kgs
Gross Weight		5.5 kgs	7.8 kgs	10 kgs
Cartons per Pallet		50 ctns = 5,000 gowns total qty	30 ctns = 3,000 gowns total qty	30 ctns = 1,800 gowns total qty

Disclaimer: Box designs and logos of Virtus / OEM might vary based on the country of manufacture due to customs permission limitations of using the medical word in certain jurisdiction. Virtus has the right to change its propriety box design for enhancing and improving its product packaging from time to time. Packaging displayed above may or may not be the exact design of the current box design in place depending on the time of your order.



		Level 3 Surgical Gown	Level 1 - 3 Isolation Fabric Non-woven Gown
	SKU#	Level 3 (GWSL303)	Level 1 (GWNL101) Level 2 (GWNL202) Level 3 (GWNL303)
	Size	S, M, L, XL	S, M, L, XL
	Color		
	GSM	80 g	20 g - 60 g
	Length of Gown	105 - 115 cms	105 - 115 cms
	Gowns per Carton	50 pcs	50 pcs
	Carton Size	60 x 40 x 50	58 x 36 x 45
	Net Weight	8 kgs	6 kgs
	Gross Weight	9.5 kgs	7.5 kgs
	Cartons per Pallet	12 ctns = 600 gowns total qty	12 ctns = 600 gowns total qty

Disclaimer: Box designs and logos of Virtus / OEM might vary based on the country of manufacture due to customs permission limitations of using the medical word in certain jurisdiction. Virtus has the right to change its propriety box design for enhancing and improving its product packaging from time to time. Packaging displayed above may or may not be the exact design of the current box design in place depending on the time of your order.



COMPLIMENTARY DISPENSER
WILL BE PROVIDED

CERTIFICATIONS FOR GOWNS



FDA Registration Confirmation

This is to confirm that, as the US Agent, we have completed the registration activation confirmation for the **FDA Establishment Registration and Device Listing** with the US Food & Drug Administration for the Fiscal Year 2020 of

ZHANGJIAGANG ANDA PLASTIC PRODUCTS CO., LTD
No.166 Jingu, Phoenix Town Zhangjiagang, Jiangsu, 215614, CHINA

The facility registration and device listing information:

Owner/Operator Number: 10072061		
Device Listing No.	Product Code	Product Name(s)
D397015	QKR	Face Mask
D397017	LYU	Disposable Glove, PE Glove, PE Apron
D397018	FYE	PE Gown, CPE Gown, Plastic Gown

SUNGO Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this attestation until the end of the calendar year stated above, unless said registration is terminated after issuance of this attestation. SUNGO Technical Service Inc. makes no other representations or warranties, nor does this attestation make any representations or warranties to any person or entity other than the named attestation holder, for whose sole benefit it is issued. **This attestation does not denote endorsement or approval of the attestation-holder's device or establishment by the U.S. Food and Drug Administration. SUNGO Technical Service Inc. assumes no liability to any person or entity in connection with the foregoing.**

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." **The U.S. Food and Drug Administration does not issue a attestation of registration, nor does the U.S. Food and Drug Administration recognize a attestation of registration, SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.**

Reference Number: 2007US303518
Issue date: Apr.26, 2020

SUNGO Technical Service Inc.
6050 W EASTWOOD AVE APT 201
CHICAGO, ILLINOIS 60630, USA
sungo.group@yahoo.com

For and on behalf of
SUNGO Technical Service Inc.

Authorized Signature
Only used for the US Agent Signature



Compliance Report

Applicant: Zhangjiagang Anda Plastic Products Co., Ltd.
Address: No.166 Jingu Road, Phoenix Town, Zhangjiagang City, Jiangsu Province, China.

Product: HD/LDPE Glove, CPE Glove, TPE Glove, EVA Glove, PE Sleeve, PE Shoe Cover, PE Apron, Surgical Gown
Type: XS, S, M, L, XL, XXL

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. 02520
Initial Issue Date: 17 May 2016



General Manager (Signature)

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










GLOVES



































	Vinyl/PE Disposable Gloves								
 SKU#	GLOVY001								
 Material	Vinyl is a synthetic, non-bio-degradable, protein-free material made from polyvinyl chloride (PVC) and plasticizers. Since vinyl gloves are synthetic and non-biodegradable, they have a longer shelf life than latex gloves, which often break down over time.								
 Description	Gloves made from vinyl are manufactured in a way to enable stretch and versatility so they are also able to hold up against punctures, scratches and general wear and tear. They can be used for healthcare tasks, keeping hands safe from contamination. Vinyl gloves, which are made from PVC (polyvinyl chloride), are usually the cheapest latex-free gloves. In general, latex gloves offer the best protection against bacteria and viruses, while synthetic gloves provide better chemical protection.								
 Make	Machine Made								
 Country of Manufacture	Made in Thailand, Vietnam  								
 Size	S, M, L, XL								
 Color									
 GSM/ Thickness	0.06 mm to 0.08 mm								
 Places of Use	Clinics, healthcare facilities, dental clinics, pre-cleanroom gowning area, laboratories, homes, food processing industries, factories, educational institutions, parks & recreational tourism, densely populated areas and frontline.								
 Protection	Conformity & Quality Standards Check								
	Approved								
	Testing Levels Check	EN1186-1 & EN1186-5	EN 388	EN 420	ISO 13485	ISO 21871	ISO 7251	ISO 6579	ISO 6888-3
	Approved								



	Vinyl/PE Disposable Gloves
 Box Size	23 x 12 x 6
 Carton Size	25 x 26 x 32
 Weight of Product	4.5 g - 4.8 g
 Quantity per Carton	100 pcs x 10 box = 1,000 gloves
 Net Weight	5 kgs
 Gross Weight	5.5 kgs
 Cartons per Pallet	60 ctns = 60,000 pcs total qty

Disclaimer: Box designs and logos of Virtus / OEM might vary based on the country of manufacture due to customs permission limitations of using the medical word in certain jurisdiction. Virtus has the right to change its propriety box design for enhancing and improving its product packaging from time to time. Packaging displayed above may or may not be the exact design of the current box design in place depending on the time of your order.



Nitrile Disposable Gloves									
 SKU#	GLONI001								
 Material	Non-sterile, powdered or powder-free, synthetic nitrile latex. Ambidextrous, fully textured, beaded cuff coloured (blue).								
 Description	The powder-free gloves offer high flexibility, tactility, tear and chemical resistance. Nitrile gloves are designed with a special nitrile formulation so that they feel and fit like latex and allow full range of motion and excellent flexibility to minimize stress and fatigue. The gloves shall maintain their properties when stored in a dry condition at temperature not higher than 86°F.								
 Make	Machine Made								
 Country of Manufacture	Made in Thailand, Vietnam  								
 Size	XS, S, M, L, XL								
 Color	     								
 GSM/ Thickness	0.06 mm to 0.08 mm								
 Places of Use	Clinics, healthcare facilities, dental clinics, pre-cleanroom gowning area, laboratories, homes, food processing industries, factories, educational institutions, parks & recreational tourism, densely populated areas and frontline.								
 Protection	Conformity & Quality Standards Check								
	Approved								
	Testing Levels Check	EN1186-1 & EN1186-5	EN 388	EN 420	ISO 13485	ISO 21871	ISO 7251	ISO 6579	ISO 6888-3
	Approved								






























Nitrile Disposable Gloves	
 Box Size	21.5 x 12 x 5.5
 Carton Size	29 x 25 x 23
 Weight of Product	2.9 g - 4.1 g
 Quantity per Carton	100 pcs x 10 box = 1,000 gloves
 Net Weight	3.5 kgs
 Gross Weight	4.5 kgs
 Cartons per Pallet	84 ctns = 84,000 pcs total qty

Disclaimer: Box designs and logos of Virtus / OEM might vary based on the country of manufacture due to customs permission limitations of using the medical word in certain jurisdiction. Virtus has the right to change its propriety box design for enhancing and improving its product packaging from time to time. Packaging displayed above may or may not be the exact design of the current box design in place depending on the time of your order.



Disposable PE Gloves

 SKU#	GLOPE001									
 Material	Polyethylene is a man made fiber made of ethylene (a petroleum derivative; C2H4) which is polymerized and then meltspun.									
 Description	Polyethylene Gloves are our most economical glove. PE gloves are most often used for light duty tasks that require frequent glove changes. This glove has a loose fit design for easy on and off applications, and is especially useful in food service lines, deli counters, and other high volume applications.									
 Make	Machine Made									
 Country of Manufacture	Made in Thailand, Vietnam  									
 Size	S, M, L, XL									
 Color										
 GSM/ Thickness	0.05 mm to 0.06 mm									
 Places of Use	Clinics, healthcare facilities, dental clinics, pre-cleanroom gowning area, laboratories, homes, food processing industries, factories, educational institutions, parks & recreational tourism, densely populated areas and frontline.									
 Protection	Conformity & Quality Standards Check									
	Approved									
	Testing Levels Check	EN1186-1 & EN1186-5	EN 388	EN 420	ISO 13485	ISO 21871	ISO 7251	ISO 6579	ISO 6888-3	
	Approved									



	Disposable PE Gloves
 Box Size	26 x 13 x 4
 Carton Size	28 x 28 x 22
 Weight of Product	1 - 2 g
 Quantity per Carton	200 pcs x 10 box = 2,000 gloves
 Net Weight	4 kgs
 Gross Weight	4.8 kgs
 Cartons per Pallet	72 ctns = 144,000 pcs total qty

Disclaimer: Box designs and logos of Virtus / OEM might vary based on the country of manufacture due to customs permission limitations of using the medical word in certain jurisdiction. Virtus has the right to change its propriety box design for enhancing and improving its product packaging from time to time. Packaging displayed above may or may not be the exact design of the current box design in place depending on the time of your order.

CERTIFICATIONS FOR GLOVES



MDD 93/42/EEC 符合性声明 (欧盟 CE 证件)

CE DECLARATION OF CONFORMITY

Manufacturer
Name: Hebei Titans Hongsen Medical Technology Co., Ltd
Address: Eastern Industrial Zone, Nangong City, Xingtai City, Hebei, China
Declares that the MDD described hereafter
Products name and Model:
Disposable Nitrile Examination Gloves
XS, S, M, L and XL

Meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EEC
Examination gloves are classified as Class I medical devices in accordance with the
rules set out in Annex IX
Applied harmonized standards: EN455-1:2000, EN455-2:2015, EN455-3:2015,
NISO14971:2012
Applied harmonized standards: EN455-1:2000, EN455-2:2015, EN455-3:
2015, EN ISO14971:2012, EN ISO 13485:2016.
Conformity assessment procedure: Annex VII of Medical Device Directive 93/42/EEC
The CE declaration of conformity is issued under the sole responsibility of Hebei Titans
Hongsen Medical Technology Co., Ltd
The products can be placed the following CE mark.

CE

Signature: *Feng Shuang yan*
Date: April 23, 2019
Quality Supervision Organization

EC REP CERTIFICATE



CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/29052020.23

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

Zhangjiagang Anda Plastic Products Co.,Ltd
No.166 Jingu Road, Phoenix Town, Zhangjiagang, Suzhou City, Jiangsu Province, China.

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.

The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/1102/2020**



Issued on: 29/05/2020



Authorized Representative
 CMC Medical Devices & Drugs SL

Valid until: 28/05/2021

www.cmcmmedicaldevices.com

EC REP CERTIFICATE



ANNEX I Medical Device Product



Isolation Gown
(Isolation Gown, PE Sleeve, PE Shoe Cover, PE apron)

Single-use medical examination gloves
(HD/LDPE Glove, CPE Glove, TPE Glove, EVA Glove)



www.cmcmmedicaldevices.com



FDA Registration Confirmation

This is to confirm that, as the US Agent, we have completed the registration activation confirmation for the **FDA Establishment Registration and Device Listing** with the US Food & Drug Administration for the **Fiscal Year 2020** of

ZHANGJIAGANG ANDA PLASTIC PRODUCTS CO., LTD
No.166 Jingu, Phoenix Town Zhangjiagang, Jiangsu, 215614, CHINA

The facility registration and device listing information:

Owner/Operator Number: 10072061		
Device Listing No.	Product Code	Product Name(s)
D397015	QKR	Face Mask
D397017	LYU	Disposable Glove, PE Glove, PE Apron
D397018	FYE	PE Gown, CPE Gown, Plastic Gown

SUNGO Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this attestation until the end of the calendar year stated above, unless said registration is terminated after issuance of this attestation. SUNGO Technical Service Inc. makes no other representations or warranties, nor does this attestation make any representations or warranties to any person or entity other than the named attestation holder, for whose sole benefit it is issued. **This attestation does not denote endorsement or approval of the attestation-holder's device or establishment by the U.S. Food and Drug Administration.** SUNGO Technical Service Inc. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue an attestation of registration, nor does the U.S. Food and Drug Administration recognize an attestation of registration, SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.

Reference Number: 2007US303518
Issue date: Apr. 26, 2020

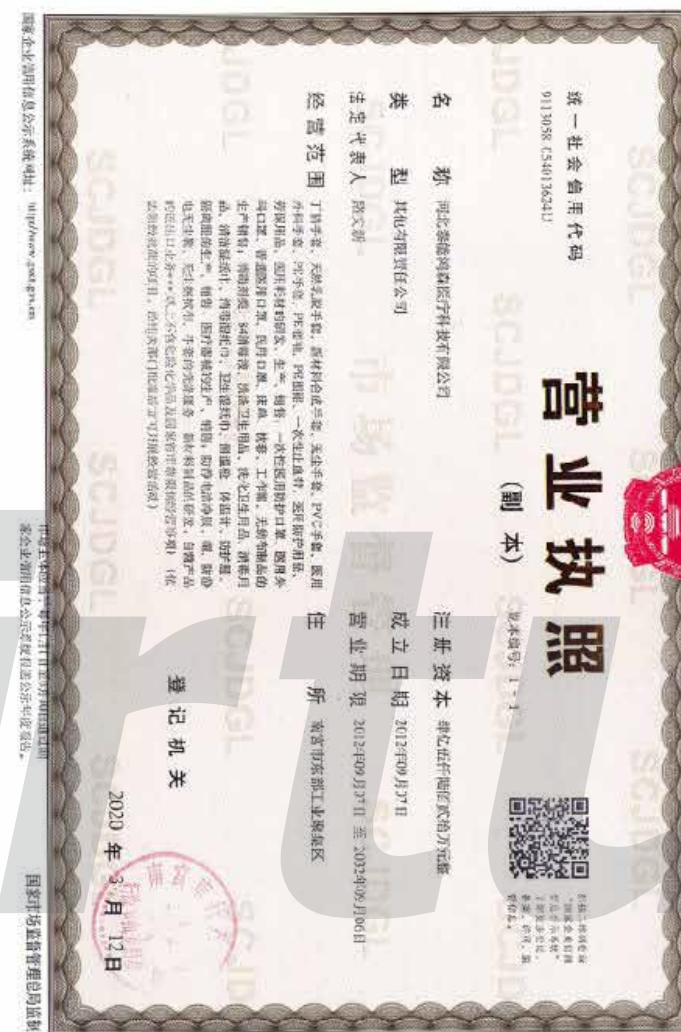
SUNGO Technical Service Inc.
6050 W EASTWOOD AVE APT 201
CHICAGO, ILLINOIS 60630, USA
sungo.group@yahoo.com

For and on behalf of
SUNCO Technical Services Inc.

Authorized Signature
Only used for the US Agent Signature



营业执照



一次性医用丁腈检查手套 FDA 证书 (1)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - W066-G609
Silver Spring, MD 20993-0002

June 18, 2015

HEBEI HONGSEN PLASTICS TECHNOLOGY CO., LTD

C/O Mr. Ray Wang

Beijing Believe Tech. Service Co., LTD

1-202, Build 3, Beijing New World, No. 5 Chaoyang Rd.

Chaoyang District, Beijing, 100024

China

Re: K150340

Trade/Device Name: POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue)

Regulation Number: 21 CFR 880.6250

Regulation Name: NITRILE Patient Examination Gloves (Power Free)

Regulatory Class: I

Product Code: LZA

Dated: May 14, 2015

Received: May 18, 2015

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

一次性医用丁腈检查手套 FDA 证书 (2)

Page 2 - Mr. Wang

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tejaswini Parohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

一次性医用 PVC 检查手套 FDA 证书(1)



September 21, 2018

Hebei Titans Hongsan Medical Technology Co., LTD.
Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5
YiHe North Rd., FangShan District
Beijing, 102401 Cn

Re: K182043

Trade/Device Name: Single-use medical poly (vinyl chloride) examination glove (Clear, Non-Colored)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LYZ
Dated: July 23, 2018
Received: July 30, 2018

Dear Ray Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

一次性医用 PVC 检查手套 FDA 证书(2)

Page 2 - Ray Wang

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

泰能鸿森公司产品 CE 注册文件 (1)

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMD/V)
Formularnummer 00272102

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für Medizinprodukte, außer In-vitro-Diagnostika
Form for Medical Devices except In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority	
Code DE/CA22	
Bezeichnung / Name Bezirksregierung Münster, Dezernat 24	
Staat / State Deutschland	Land / Federal state Nordrhein-Westfalen
Ort / City Münster	Postleitzahl / Postal code 48143
Straße, Haus-Nr. / Street, house no. Domplatz 36	
Telefon / Phone +49-251-4110	Telefax / Fax +49-251-4112525
E-Mail / E-mail mitteilungen-dimdi@brms.nrw.de	
Anzeige / Notification	
Registriertatum bei der zuständigen Behörde Registration date at competent authority 03.05.2019	Registriernummer / Registration number DE/CA22/419-832.2
Typ der Anzeige / Notification type • Erstanzeige / Initial notification • Änderungsanzeige / Notification of change • Widerrufsanzeige / Notification of withdrawal	
Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn DE/CA22/419-832.1	
Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG • Hersteller / Manufacturer • Bevollmächtigter / Authorised Representative • Einführer / Importer • Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG • Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV • Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG	

泰能鸿森公司产品 CE 注册文件 (2)

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMD/V)
Formularnummer 00272102

Anzeigender / Reporting organisation (person)	
Code DE/0000012115	
Bezeichnung / Name MedNet GmbH	
Staat / State Deutschland	Land / Federal state Nordrhein-Westfalen
Ort / City Münster	Postleitzahl / Postal code 48163
Straße, Haus-Nr. / Street, house no. Borkstrasse 10	
Telefon / Phone +49-251-32266-0	Telefax / Fax +49-251-32266-22
E-Mail / E-mail info@medneteurope.com	
Hersteller / Manufacturer	
Bezeichnung / Name Hebei Titans Hongsen Medical Technology Co., Ltd.	
Staat / State CN	
Ort / City Nangong City, Xingtai City, Hebei Province	Postleitzahl / Postal code 051800
Straße, Haus-Nr. / Street, house no. Eastern Industrial Zone	
Telefon / Phone +86 -311-85370099	Telefax / Fax
E-Mail / E-mail	
Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG	
Bezeichnung / Name Nicole Böhnisch	
Staat / State Deutschland	Land / Federal state Nordrhein-Westfalen
Ort / City MÜNSTER	Postleitzahl / Postal code 48163
Straße, Haus-Nr. / Street, house no. Borkstrasse 10	
Telefon / Phone +49-251-32266-0	Telefax / Fax +49-251-32266-22
E-Mail / E-mail info@medneteurope.com	



泰能鸿森公司产品 CE 注册文件（3）

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDV)
Formularnummer 00272102

Vertreter / Deputy (optional)	
Bezeichnung / Name Kristin Zurlinden	
Telefon / Phone +49 251 32266 0	Telefax / Fax +49 251 32266 22
E-Mail / E-mail info@medneteuropa.com	
<ul style="list-style-type: none">• Erstanzeige / Initial notification• Änderungsanzeige / Notification of change	



泰能鸿森公司产品 CE 注册文件（4）

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDV)
Formularnummer 00272102

Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)	
Klasse / Class	
<ul style="list-style-type: none">• I• I - steril / sterile• I - mit Messfunktion / with measuring function• I - steril und mit Messfunktion / sterile and with measuring function• IIa• IIb• III• III - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012• Aktives implantierbares Medizinprodukt / Active implantable medical device• Aktives implantierbares Medizinprodukt - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 Active implantable medical device - manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012	
App (Software auf mobilen Endgeräten)	<input type="checkbox"/> ja / yes <input type="checkbox"/> nein / no
Nummer(n) der Bescheinigung(en) / Certificate number(s)	
Handelsname des Produktes / Trade name of the device	
Produktbezeichnung / Name of device Single-use Nitrile Patient Examination Gloves, Single-use Examination Vinyl Gloves	
Nomenklaturcode / Nomenclature code 11-882	
Nomenklaturbezeichnung / Nomenclature term Handschuh, Untersuchung/Behandlung	
Kategoriecode / Category code 10	
Kategorie / Category Produkte zum Einmalgebrauch	
Kurzbeschreibung deutsch / German short description	
Kurzbeschreibung englisch / English short description	



泰能鸿森公司产品 CE 注册文件（5）

Anlage 1
Du § 4 Abs. 1 Nr. 1 StBGV
Formularnummer 002/2102

Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)	
<ul style="list-style-type: none">Semikritische Medizinprodukte / Semicritical medical devices<ul style="list-style-type: none">Gruppe A / Group AGruppe B / Group BKritische Medizinprodukte / Critical medical devices<ul style="list-style-type: none">Gruppe A / Group AGruppe B / Group BGruppe C / Group C	Nummer der Bescheinigung / Certificate number
Sterilisationsverfahren / Sterilisation procedures <ul style="list-style-type: none">Dampfsterilisation / Steam sterilisationGassterilisation / Gas sterilisationStrahlensterilisation / Radiation sterilisationandere / others	
Angewandtes Verfahren / Applied procedure	

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort / City: Münster Datum / Date: 2019-02-04
Name: Nicole Böhnisch Unterschrift / Signature

Bearbeitungsvermerke / Processing notes	
Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority	
Bearbeiter / Person responsible <u>Frau Silvia Wenge</u>	Telefon / Phone <u>0251-4119936</u>



MDD 93/42/EEC 符合性声明
(欧盟 CE 证件)

CE DECLARATION OF CONFORMITY

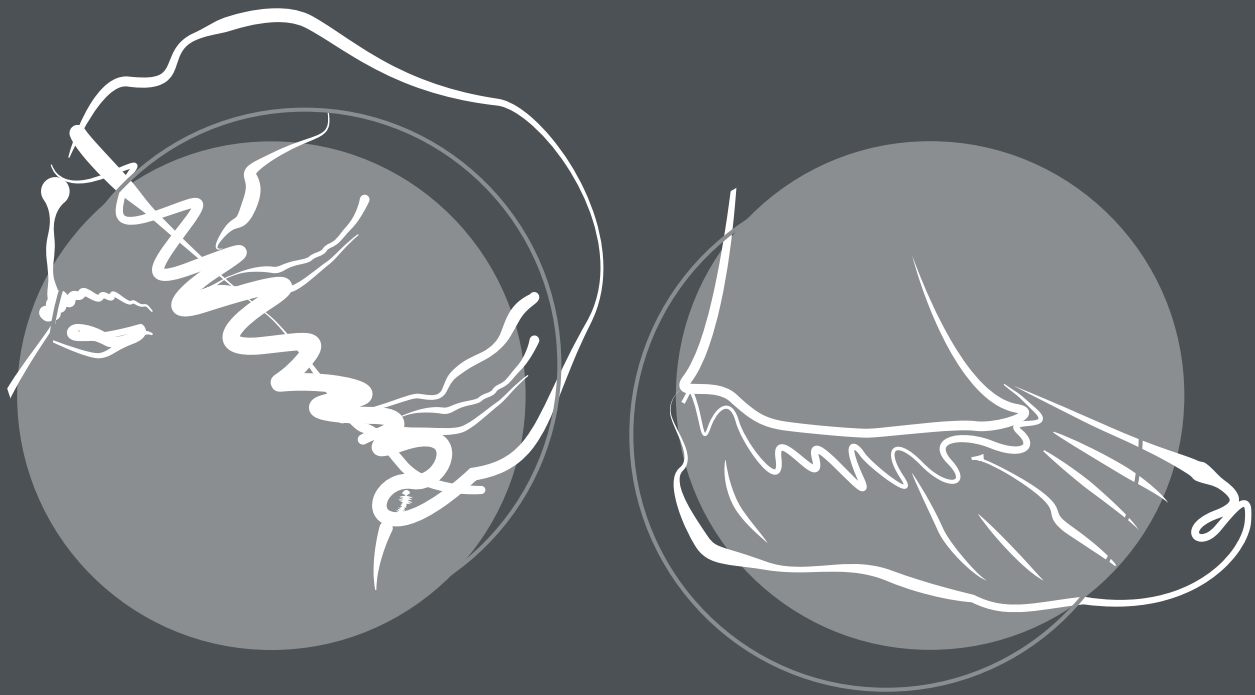
Manufacturer
Name: Hebei Titans Hongsen Medical Technology Co., Ltd
Address: Eastern Industrial Zone, Nangong City, Xingtai City, Hebei, China
Declares that the MDD described hereafter
Products name and Model:
Disposable Nitrile Examination Gloves
XS, S, M, L and XL












Meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EEC
Examination gloves are classified as Class I medical devices in accordance with the rules set out in Annex IX
Applied harmonized standards: EN455-1:2000, EN455-2:2015, EN455-3:2015, NISO14971:2012
Applied harmonized standards: EN455-1: 2000, EN455-2: 2015, EN455-3: 2015, EN ISO14971:2012, EN ISO 13485:2016
Conformity assessment procedure: Annex VII of Medical Device Directive 93/42/EEC
The CE declaration of conformity is issued under the sole responsibility of Hebei Titans Hongsen Medical Technology Co., Ltd
The products can be placed the following CE mark.

CE

Signature: Feng Shuang yan
Date: April 23, 2019
Quality Supervision Organization

BOUFFANT CAPS & SHOE COVERS



	Bouffant Caps Hand Made (made to order)	Bouffant Caps Machine Made (Standard)	Shoe Covers
<div>SKU#</div>	BOUHM001	BOUMM001	SPGOO001
<div>Material</div>	Non-woven spun bonded Polypropylene.	Non-woven spun bonded Polypropylene.	Non-woven spun bonded Polypropylene.
<div>Country of Manufacture</div>	Made in China 	Made in China 	Made in China 
<div>GSM</div>	30 gsm	18 gsm	40 gsm
<div>Size</div>	Universal	Universal	Universal
<div>Characteristics</div>	Soft elasticated head covers, 100% latex-free. Avoids escape of hair, dandruff & micro organisms, providing safety during procedures. Preferred for it's light weight.	Soft elasticated head covers, 100% latex-free. Avoids escape of hair, dandruff & micro organisms, providing safety during procedures. Preferred for it's light weight.	Stretch design suitable for shoes, ensuring maximum coverage. Breatheable and soft, makes you feel comfortable. Excellent elasticity, high quality.
<div>Places of Use</div>	Clinics, healthcare facilities, dental clinics, pre-cleanroom gowning area, laboratories, homes, food processing industries, factories, educational institutions, parks & recreational tourism, densely populated areas and frontline.		
<div>Color</div>	 	 	 
<div>Protection</div>	Conformity & Quality Standards Check		
	Approved		





		Bouffant Caps Hand Made (made to order)
	Box Size	58 x 28 x 36
	Pieces	2,000 pcs
	Weight of product	3 g
	Carton Net weight	2.8 kgs
	Carton Gross Weight	3.5 kgs
	Number of Cartons per Pallet	24 ctns = 48,000 pcs total qty

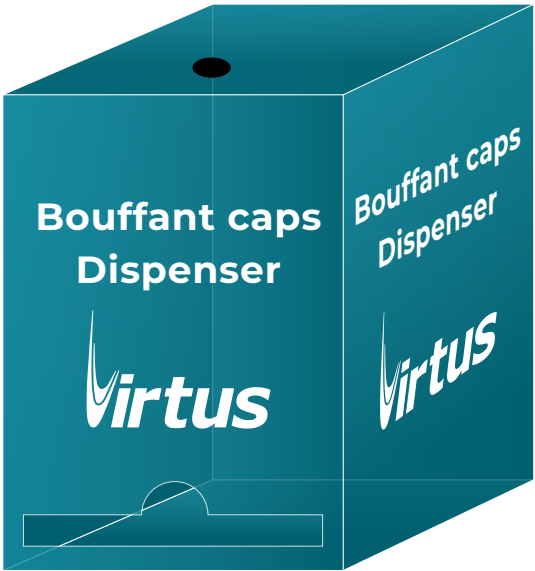


		Bouffant Caps Machine Made (Standard)
	Box Size	58 x 28 x 36
	Pieces	2,000 pcs
	Weight of product	3 g
	Carton Net weight	2.8 kgs
	Carton Gross Weight	3.5 kgs
	Number of Cartons per Pallet	24 ctns = 48,000 pcs total qty



		Shoe Covers
	Box Size	58 x 37 x 38
	Pieces	4,000 pcs
	Weight of product	3 g
	Carton Net weight	3 kgs
	Carton Gross Weight	3.8 kgs
	Number of Cartons per Pallet	16 ctns = 64,000 pcs total qty

Disclaimer: Box designs and logos of Virtus / OEM might vary based on the country of manufacture due to customs permission limitations of using the medical word in certain jurisdiction. Virtus has the right to change its propriety box design for enhancing and improving its product packaging from time to time. Packaging displayed above may or may not be the exact design of the current box design in place depending on the time of your order.



COMPLIMENTARY DISPENSERS
WILL BE PROVIDED

CERTIFICATIONS
FOR BOUFFANT CAPS
& SHOE COVERS




国家企业信用信息公示系统网址: <http://www.gsxt.gov.cn> 市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。 国家市场监督管理总局监制



国家企业信用信息公示系统网址: <http://www.gsxt.gov.cn> 市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。 Supervised by the State Administration for Market Regulation

(translated from the original Chinese certificate)





Compliance Report

Applicant: Zhangjiagang Anda Plastic Products Co., Ltd.
Address: No.166 Jingu Road, Phoenix Town, Zhangjiagang City, Jiangsu Province, China.

Product: HD/LDPE Glove, CPE Glove, TPE Glove, EVA Glove, PE Sleeve, PE Shoe Cover, PE Apron, Surgical Gown
Type: XS, S, M, L, XL, XXL

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. 02520
Initial Issue Date: 17 May 2016









Tony Chen
General Manager (Signature)

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

HYGIENE SOLUTIONS












HAND SANITIZERS



	Antibacterial Hand Sanitizer with Skin Moisturizer
 Material	Inactive ingredients: Propylene glycol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Perfume, purified water. Kills 99.9% Germs, 75% AlchoholEthyl Alcohol 80% v/v Antiseptic.
 Description of Product with Characteristics	Hand sanitizer helps reduce bacteria that can potentially cause disease. For use when soap and water is not available.
 Country of Manufacture	Made in UAE 
 Fragrance	Lemon, Aqua & Eucalyptus
 Protection	Kills 99.99% Germs
 Shelf Life	2 years
 Places of Use	Clinics, healthcare facilities, dental clinics, pre-cleanroom gowning area, laboratories, homes, food processing industries, factories, educational institutions, parks & recreational tourism, densely populated areas and frontline.





Antibacterial Hand Sanitizer with Skin Moisturizer				
	SKU#	SANXL001 SANXL002 SANXL003	SANLL001 SANLL002 SANLL003	SANMM001 SANMM002 SANMM003
	Weight of Product	169 Oz	16.91 Oz	8.12 Oz
	Color			
	Carton Size	work in prgress	232 X 216 X 173 MM	423 X 232 X 173 MM
	Quantity per Carton	work in prgress	500 ML X 12 pcs	250 ML X 24 pcs
	Net Weight	work in prgress	5.22 kgs	5.22 kgs
	Gross Weight	work in prgress	6.05 kgs	6.27 kgs
	Cartons per Pallet	work in prgress	78	78

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CERTIFICATION FOR HAND SANITIZER



Test Report DA20-12481.001 R0

Customer: Seville Products LLC P.O.Box 10596, Umm Ramool Rashidiya Dubai United Arab Emirates	Job Number: DA20-12481
Received: 06/04/2020	Approved: 09/04/2020
Reported: 25/04/2020	Page: 1/1
Description: Guardex Hand Sanitizer With Ethanol	
Packaging type: Plastic bottle	Production date: 05.04.2020

Chemical testing

Analysis	Method	RL	Result	Uncert	Unit	Standard Limits
Ethanol Content ^①	FL-SOP-TECH-069	0.01	84.85		% (w/v)	--
Methanol Content ^①	FL-SOP-TECH-070	0.01	<0.01		%	--
Viscosity	By Viscometer	--	12160.00		cP	--

^① are accredited by EIAAC

Remarks:
Sample description is declared by Customer.
Uncertainty will be reported on Customer request.
Test method deviation: none.
RTF - Results to Follow, ND - Not Detected, N/A - Not Available, CFU - Colony Forming Units, EAPC - Estimated Aerobic plate count, LPS - Limits as per Standard, Temp. - Temperature, TNTC - Too Numerous to Count, RL - Reporting Limit (method quantification limit), ppm - parts per million, ppb - parts per billion.
Result with symbol "<" are considered as not detected except "<250 EAPC".

As per Dubai Municipality circular dated 24.03.2020, methanol content (methyl alcohol - CASno:67-56-1) in hand sanitizer is prohibited

Date Start/End Analysis : 09/04/2020



Tina Sanan
Laboratory Manager

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FCL/FIC/024 Rev 07, Dated 14/05/2019

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Test Report DA20-12390.001 R0

Customer: Seville Products LLC P.O.Box 10596, Umm Ramool Rashidiya Dubai United Arab Emirates	Job Number: DA20-12390
Received: 30/03/2020	Approved: 13/04/2020
Reported: 22/04/2020	Page: 1/2
Description: Guardex Hand Sanitizer With Ethanol	

Chemical testing

Analysis	Method	RL	Result	Uncert	Unit	Standard Limits
Cadmium ^①	FL-SOP-TECH-119 by ICP-MS	0.10	<0.10		ppm	--
Lead ^①	FL-SOP-TECH-119 by ICP-MS	0.10	<0.10		ppm	--
Mercury ^①	FL-SOP-TECH-119 by ICP-MS	0.10	<0.10		ppm	--
Antimony ^①	FL-SOP-TECH-119 by ICP-MS	0.10	<0.10		ppm	--
Arsenic ^①	FL-SOP-TECH-119 by ICP-MS	0.10	<0.10		ppm	--
pH ^①	FL-SOP-TECH-065	--	7.14		-	--
Specific Gravity	In-house method	--	0.8803		g/cm3	--

^① are accredited by EIAAC

Remarks:
Sample description is declared by Customer.
Uncertainty will be reported on Customer request.
Test method deviation: none.
RTF - Results to Follow, ND - Not Detected, N/A - Not Available, CFU - Colony Forming Units, EAPC - Estimated Aerobic plate count, LPS - Limits as per Standard, Temp. - Temperature, TNTC - Too Numerous to Count, RL - Reporting Limit (method quantification limit), ppm - parts per million, ppb - parts per billion.
Result with symbol "<" are considered as not detected except "<250 EAPC".

Date Start/End Analysis : 30/03/2020 - 06/04/2020



Tina Sanan
Laboratory Manager

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TEST REPORT – MICROBIOLOGY

Customer Name:	Seville Products LLC
Address:	P.O.Box 10596, Umm Ramool, Rashidiya, Dubai
Contact details:	Mr. Nitesh Om Parkash Bhalla
E-mail:	nparkash@iffco.com
Date received:	30.03.2020
Sample No.:	12390.001
Date of Report:	16.04.2020
Report No.:	DA20.12390.001
Job No.:	DA19-12390
Packaging type:	Sealed Bottle
Packaging condition:	-
Sample collected on:	-
Sample name:	Guardex Hand Sanitizer With Ethanol
Sample collected by:	-
Sample Receipt Temp.:	-
Dates of analysis:	30/03/2020 - 13/04/2020
Page No.:	1/2
Batch no:	-

Experimental Conditions:

Product Test Concentration	Direct
Test method	EN 1276 - Dilution neutralization
Contact Time	1 Minute
Test Temperature	20°C
Interfering Substance	3% Bovine albumin
Incubation Temperature	37±1°C
Neutralizer	Polysorbate 80
Bacterial Strains Used	<i>Pseudomonas aeruginosa</i> - ATCC15442 <i>Staphylococcus aureus</i> - ATCC 6538 <i>Enterococcus hirae</i> - ATCC 10541 <i>Escherichia coli</i> - ATCC 10536

Test Organisms	<i>Pseudomonas aeruginosa</i>	<i>Staphylococcus aureus</i> ☑	<i>Escherichia coli</i> ☑	<i>Enterococcus hirae</i> ☑
Validation suspension N_{v0}	Vc1:140 Vc2:136 \bar{X} : 138	Vc1:130 Vc2:134 \bar{X} : 122	Vc1:120 Vc2:142 \bar{X} : 140	Vc1:125 Vc2:129 \bar{X} : 127
Experimental control	Vc1:122 Vc2:114 \bar{X} : 118 ≥ 0.5 N_{v0}	Vc1:121 Vc2:135 \bar{X} : 128 ≥ 0.5 N_{v0}	Vc1:122 Vc2:122 \bar{X} : 122 ≥ 0.5 N_{v0}	Vc1:128 Vc2:152 \bar{X} : 140 ≥ 0.5 N_{v0}

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Neutraliser control	Vc1:135 \bar{X} : 128 ≥ 0.5 N_{v0}	Vc2:121 \bar{X} : 132 ≥ 0.5 N_{v0}	Vc1:130 \bar{X} : 122 ≥ 0.5 N_{v0}	Vc2:134 \bar{X} : 122 ≥ 0.5 N_{v0}	Vc1:121 \bar{X} : 110 ≥ 0.5 N_{v0}	Vc2:123 \bar{X} : 115 ≥ 0.5 N_{v0}	Vc1:124 \bar{X} : 126 ≥ 0.5 N_{v0}	Vc2:128 \bar{X} : 126 ≥ 0.5 N_{v0}
Method validation	Vc1:98 \bar{X} : 94 ≥ 0.5 N_{v0}	Vc2:90 \bar{X} : 100 ≥ 0.5 N_{v0}	Vc1:104 \bar{X} : 110 ≥ 0.5 N_{v0}	Vc2:96 \bar{X} : 115 ≥ 0.5 N_{v0}	Vc1:112 \bar{X} : 110 ≥ 0.5 N_{v0}	Vc2:108 \bar{X} : 115 ≥ 0.5 N_{v0}	Vc1:120 \bar{X} : 115 ≥ 0.5 N_{v0}	Vc2:110 \bar{X} : 115 ≥ 0.5 N_{v0}
Test suspension	10^6 Vc1:190 10^7 Vc1:22	Vc2:198 Vc2:18	Vc1:192 Vc1:18	Vc2:200 Vc2:26	Vc1:182 Vc1:30	Vc2:184 Vc2:26	Vc1:168 Vc1:18	Vc2:172 Vc2:14
(N) (N_{v0} = N/10)	\bar{w} : 1.9x 10^8 Ig N : = 8.28 Ig N_{v0} : = 7.28	\bar{w} : 1.9 10^8 Ig N : = 8.29 Ig N_{v0} : = 7.29	\bar{w} : 1.9 10^8 Ig N : = 8.29 Ig N_{v0} : = 7.29	\bar{w} : 1.9x 10^8 Ig N : = 8.28 Ig N_{v0} : = 7.28	\bar{w} : 1.7x10 ⁸ Ig N : = 8.22 Ig N_{v0} : = 7.22	\bar{w} : 1.7x10 ⁸ Ig N : = 8.22 Ig N_{v0} : = 7.22	\bar{w} : 1.7x10 ⁸ Ig N : = 8.22 Ig N_{v0} : = 7.22	\bar{w} : 1.7x10 ⁸ Ig N : = 8.22 Ig N_{v0} : = 7.22
Results: (Na) (R) (Ig N_{v0} - Ig Na)	Vc1:0 \bar{X} x10 : <10 Ig Na : <1.0 Ig R : 6.28	Vc1:0 \bar{X} x10 : <10 Ig Na : <1.0 Ig R : 6.29	Vc1:0 \bar{X} x10 : <10 Ig Na : <1.0 Ig R : 6.29	Vc1:0 \bar{X} x10 : <10 Ig Na : <1.0 Ig R : 6.28	Vc1:0 \bar{X} x10 : <10 Ig Na : <1.0 Ig R : 6.28	Vc1:0 \bar{X} x10 : <10 Ig Na : <1.0 Ig R : 6.28	Vc1:0 \bar{X} x10 : <10 Ig Na : <1.0 Ig R : 6.22	Vc1:0 \bar{X} x10 : <10 Ig Na : <1.0 Ig R : 6.22
Pass: Ig R ≥ 5	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

NA- Not Applicable, CFU - Colony Forming Units, Vc - Plate count, X - Average of Vc1 and Vc2, \bar{w} - Weighed mean of \bar{X} , R - Reduction (Ig R = Ig N_{v0} - Ig Na)

Based on EN 1276 (2009), the tested product possesses bactericidal activity in 1 minute at 20°C under dirty condition



TINA SANAN
Laboratory Manager









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THERMOMETER



	Thermometer
 Material	ABS/Infrared sensor/PCB
 Description of Product with Characteristics	Surface temperature measurement
 Make	Machine
 Country of Manufacture	Made in China 
 Color	White + Purple
 Size	Unisex
 Places of Use	Hospital or other





Thermometer			
	SKU#		
	Weight of Product	0.0844 kg	
	Color	 	
	Size of Product	190 x 140 x 50 mm	175 x 105 x 40 mm
	GSM	0.147 kg	0.126 kg
	Bulk Box Dimensions	190 x 140 x 50 mm	175 x 105 x 40 mm
	Carton Size	520 x 295 x 400 mm	545 x 375 x 220 mm
	Quantity per Carton	40 pcs	50 pcs
	Net Weight	6.0 kg	6.3 kg
	Gross Weight	6.7 kg	6.9 kg
	Cartons per Pallet	30 ctns	42 ctns

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CERTIFICATION FOR THERMOMETER



Shenzhen JT Detection Technology Co., Ltd

EMC Test Report



Product : infrared radiation thermometer
Model Number : JJT889
Prepared for : Shenzhen Chuang Cheng Da Electronic Technology Co., Ltd.
Address : No.2 Gaoying Industrial Zone,Pulong West Road,
Tangxia Town,Dongguan City
Report Number : E0312-CCD
Date of Test : Mar 09,2020
Date of Rep. : Mar 09,2020-Mar 12,2020

Prepared by(Engineer):

Reviewer(Quality Manager):

Approved & Authorized Signer(Manager):



Shenzhen JT Detection Technology Co., Ltd

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2 Test Summary

Test IU-DQX08cedures according to the technical standards:

EMC Emission				
Standard	Test Item	Limit	Judgment	Remark
EN 55014-1: 2017+A1:2009+A2: 2011	Conducted Emission	Class B	PASS	
	Radiated Emission	Class B	PASS	
EN61000-3-2: 2014+A2: 2009	Harmonic Current Emission	Class A or D NOTE (2)	PASS	
EN 61000-3-3: 2013	Voltage Fluctuations & Flicker	-----	PASS	
EMC Immunity				
Section	Test Item	Performance Criteria	Judgment	Remark
EN55014-2:2015+A1: 2001+A2: 2008				
EN 61000-4-2: 2009	Electrostatic Discharge	B	PASS	
EN 61000-4-3:2006+A1:2008+A2:2 010	RF electromagnetic field	A	PASS	
EN 61000-4-4: 2012	Fast transients	B	PASS	
EN 61000-4-5: 2006	Surges	B	PASS	
EN 61000-4-6: 2012	Injected Current	A	PASS	
EN 61000-4-11: 2004	Volt. Interruptions Volt. Dips	C / C / C NOTE (3)	PASS	

NOTE:

(1)' N/A' denotes test is not applicable in this Test Report

(2) No limits apply for equipment with an active input power up to and including 75W.

(3)Voltage dip: 0% reduction – Performance Criteria **C**
Voltage dip: 30% reduction – Performance Criteria **C**
Voltage dip: 60% reduction – Performance Criteria **C**
For client's request and manual description, the test will not be executed.



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3 General Information

3.1 General Description Of EUT

Manufacturer:	Shenzhen Chuang Cheng Da Electronic Technology Co., Ltd.
Manufacturer Address:	No.2 Gaoying Industrial Zone,Pulong West Road,Tangxia Town, Dongguan City
EUT Name:	infrared radiation thermometer
Test Model No:	JJT889
Attached No.:	/
Brand Name:	小疆创新 JJT889
Power Supply Range:	3V
Test Power Supply:	/



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4 Equipments List For All Test Items

No.	Equipment	Manufacturer	Model No.	S/N	Cal date
1	EMI Test Receiver	R&S	ESCI	100612	2021-04-08
2	EMI Test Receiver	R&S	ESPI	100067	2021-04-08
3	Amplifier	HP	8447D	1937A02415	2021-04-08
4	Single Power Conductor Module	FCC	FCC-LISN-5-50-1-01-CISPR25	07118	2021-04-08
5	TRILOG Broadband Test-Antenna	SCHWARZBECK	VULB9163	9163-387	2021-04-08
6	Horn Antenna	SCHWARZBECK	BBHA9120A	B08000991-0021	2021-04-08
7	High Field Biconical Antenna	ELECTRO-METRICS	EM-6913	169	2021-04-08
8	Log Periodic Antenna	ELECTRO-METRICS	EM-6950	818	2021-04-08
9	Remote Active Vertical Antenna	ELECTRO-METRICS	EM-6892	354	2021-04-08
10	Power Clamp	SCHWARZBECK	MDS-21	3898	2021-04-08
11	Single Power Conductor Module	FCC	FCC-LISN-5-50-1-01-CISPR25	07254	2021-04-08
12	Teo Line Single Phase Module	SCHWARZBECK	NSLK8128	D-69124	2021-04-08
13	Positioning Controller	C&C	CC-C-1F	MF7802155	2021-04-08
14	Electrostatic Discharge Simulator	TESEQ	NSG437	128	2021-04-08
15	Fast Transient Burst Generator	SCHAFFNER	MODULA6150	34587	2021-04-08
16	Fast Transient Noise Simulator	Noiseken	FNS-105AX	31438	2021-04-08
17	Capacitive Coupling Clamp	TESEQ	CDN8014	25115	2021-04-08
18	Color TV Pattern Generator	PHILIPS	PM5418	TM209966	N/A
19	Power Frequency Magnetic Field Gene	EVERFINE	EMS61000-8K	608085	2021-04-08
20	Triple-Loop Antenna	EVERFINE	LLA-2	607035	2021-04-08
21	10dB attenuator	SCHWARZBECK	MTAIMP-136	R65.90.0009	2021-04-08



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5 Emission Test Results

5.1 Mains Terminals Disturbance Voltage Measurement

Frequency Range:	150kHz to 30MHz
Limits:	Table 1 of EN 55014-1
Detector:	Peak for pre-scan (9kHz Resolution Bandwidth) Quasi-Peak & Average if maximized peak within 6dB of Average Limit

5.1.1 E.U.T. Operation

Operating Environment:						
Temperature:	21°C	Humidity:	63% RH	Atmospheric Pressure:	102.0	Kpa
EUT Operation:	Connect EUT output to dummy load.					

5.1.2 Test Specification

EUT was placed upon a wooden test table 0.8m above the horizontal metal plane and 0.4m from the vertical metal reference plane, and it was connected to an AMN. The closest distance between the boundary of the EUT and the surface of the AMN is 0.8m, All peripherals were connected to another AMN, and placed at a distance of 10 cm from each other. A spectrum and receiver was connected to the RF output port of the AMN. Both average and quasi-peak value were detected.

Associated with the conducted emission test data in this report is a ±1.54dB measurement uncertainty.



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5.1.3 Measurement Data

An initial pre-scan was performed on the live and neutral lines.
Quasi-peak or average measurements were performed at the frequency which maximum peak emissions were detected.
Please refer to the attached quasi-peak & average measurement data for reference.

Line

Frequency (MHz)	Factor (dB)	Quasi-peak				Average			
		Reading Level (dBuV)	Measure Level (dBuV)	Limit (dBuV)	Margin (dB)	Reading Level (dBuV)	Measure Level (dBuV)	Limit (dBuV)	Margin (dB)
0.242	10.163	39.200	49.363	63.371	-14.008	28.900	39.065	53.343	-14.278
0.307	10.235	36.300	46.535	61.514	-14.979	29.700	39.936	51.486	-11.550
0.439	10.324	34.000	44.324	57.743	-13.419	30.100	40.425	47.686	-7.261
* 0.573	10.382	32.800	43.182	56.000	-12.818	29.400	39.782	46.000	-6.218
1.849	10.540	32.700	43.240	56.000	-12.760	27.400	37.940	46.000	-8.060
5.659	10.680	27.300	37.980	60.000	-22.020	22.400	33.080	50.000	-16.920

Neutral

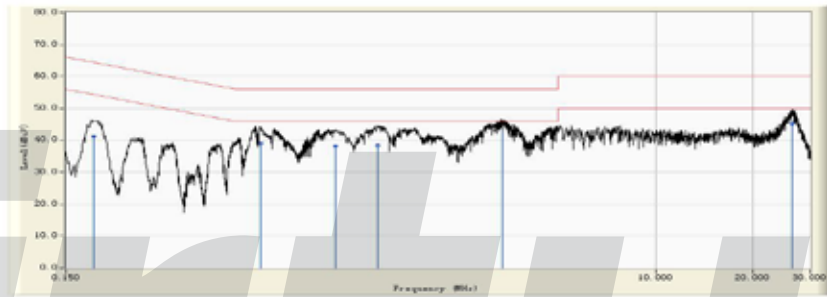
Frequency (MHz)	Factor (dB)	Quasi-peak				Average			
		Reading Level (dBuV)	Measure Level (dBuV)	Limit (dBuV)	Margin (dB)	Reading Level (dBuV)	Measure Level (dBuV)	Limit (dBuV)	Margin (dB)
0.242	10.163	39.200	49.363	63.371	-14.008	28.900	39.065	53.343	-14.278
0.307	10.235	36.300	46.535	61.514	-14.979	29.700	39.936	51.486	-11.550
0.439	10.324	34.000	44.324	57.743	-13.419	30.100	40.425	47.686	-7.261
* 0.573	10.382	32.800	43.182	56.000	-12.818	29.400	39.782	46.000	-6.218
1.849	10.540	32.700	43.240	56.000	-12.760	27.400	37.940	46.000	-8.060
5.659	10.680	27.300	37.980	60.000	-22.020	22.400	33.080	50.000	-16.920

Note: “*” means the worst case
Measurement Level = Reading Level + Factor
Factor = Cable Loss + LISN insertion loss



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TEL: 86-0755-23727386 http://www.jt-jiance.com	
Engineer: Aaron	
Site: conduction test site	Time: Mar 09, 2020
Limit: EN 55014_B_03M_QP	Margin: 10
EUT: infrared radiation thermometer	Model: JJT889
POWER: 3V	Note: PREVIEW



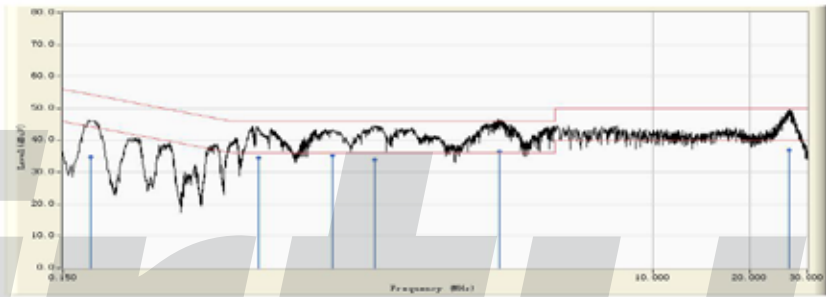
	Frequency (MHz)	Correct Factor (dB)	Reading Level (dBuV)	Measure Level (dBuV)	Margin (dB)	Limit (dBuV)	Detector Type
1	0.183	10.073	31.200	41.273	-23.784	65.057	QUASIPeAK
2	0.901	10.392	28.600	38.992	-17.008	56.000	QUASIPeAK
3	1.016	10.470	27.600	38.070	-17.930	56.000	QUASIPeAK
4	1.383	10.493	26.000	36.493	-17.507	56.000	QUASIPeAK
5 *	3.367	10.630	34.600	45.230	-10.770	56.000	QUASIPeAK
6	26.300	11.290	33.900	45.190	-14.810	60.000	QUASIPeAK

Note:
1. All Reading Levels are Quasi-Peak and average value.
2. " * ", means this data is the worst emission level.
3. Measurement Level = Reading Level + Correct Factor



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POWER: 3V	Note: PREVIEW



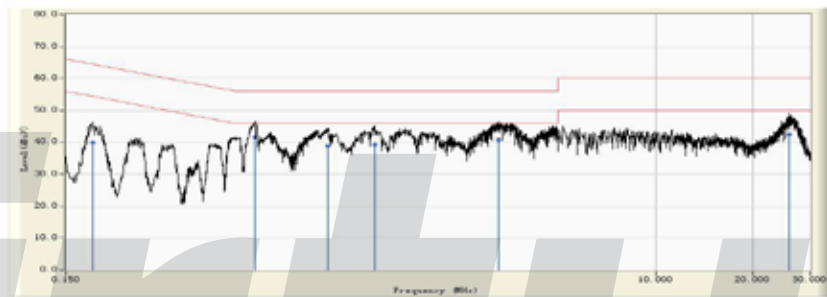
	Frequency (MHz)	Correct Factor (dB)	Reading Level (dBuV)	Measure Level (dBuV)	Margin (dB)	Limit (dBuV)	Detector Type
1	0.183	10.073	24.600	34.673	-20.384	55.057	AVERAGE
2	0.905	10.395	24.100	34.495	-11.505	46.000	AVERAGE
3	1.016	10.470	24.600	35.070	-10.930	46.000	AVERAGE
4	1.383	10.493	23.400	33.893	-12.107	46.000	AVERAGE
5 *	3.363	10.630	25.800	36.430	-9.570	46.000	AVERAGE
6	26.300	11.290	25.600	36.890	-13.110	50.000	AVERAGE

Note:
1. All Reading Levels are Quasi-Peak and average value.
2. " * ", means this data is the worst emission level.
3. Measurement Level = Reading Level + Correct Factor



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EUT: infrared radiation thermometer	Model: JJT889
POWER: 3V	Note: PREVIEW



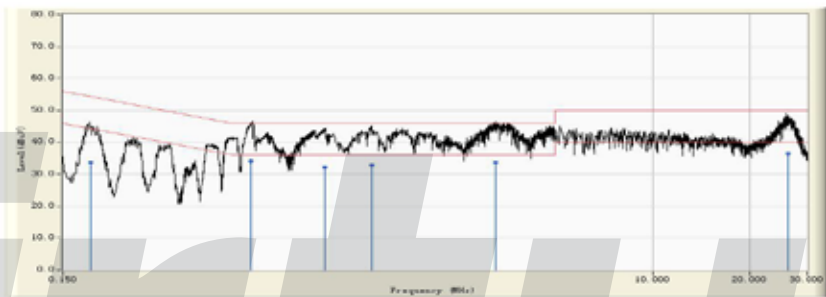
	Frequency (MHz)	Correct Factor (dB)	Reading Level (dBuV)	Measure Level (dBuV)	Margin (dB)	Limit (dBuV)	Detector Type
1	0.181	9.995	29.800	39.794	-25.320	65.114	QUASIPeAK
2 *	0.578	10.383	31.200	41.583	-14.417	56.000	QUASIPeAK
3	0.966	10.470	28.300	38.770	-17.230	56.000	QUASIPeAK
4	1.354	10.490	28.700	39.190	-16.810	56.000	QUASIPeAK
5	3.287	10.621	30.100	40.721	-15.279	56.000	QUASIPeAK
6	25.825	11.180	31.200	42.380	-17.620	60.000	QUASIPeAK

Note:
1. All Reading Levels are Quasi-Peak and average value.
2. " * ", means this data is the worst emission level.
3. Measurement Level = Reading Level + Correct Factor



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Site: conduction test site	Time: Mar 09, 2020
Limit: EN 55014_B_03M_QP	Margin: 10
EUT: infrared radiation thermometer	Model: JJT889
POWER: 3V	Note: PREVIEW



	Frequency (MHz)	Correct Factor (dB)	Reading Level (dBuV)	Measure Level (dBuV)	Margin (dB)	Limit (dBuV)	Detector Type
1	0.183	10.001	23.700	33.702	-21.356	55.057	AVERAGE
2 *	0.572	10.381	23.700	34.081	-11.919	46.000	AVERAGE
3	0.965	10.470	21.800	32.270	-13.730	46.000	AVERAGE
4	1.356	10.490	22.300	32.790	-13.210	46.000	AVERAGE
5	3.280	10.620	23.100	33.720	-12.280	46.000	AVERAGE
6	26.175	11.180	25.300	36.480	-13.520	50.000	AVERAGE

Note:
1. All Reading Levels are Quasi-Peak and average value.
2. " * ", means this data is the worst emission level.
3. Measurement Level = Reading Level + Correct Factor



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5.2Disturbance Power Measurement						
Frequency Range:		30MHz to 300MHz				
Limits:		Table 2 of EN55014-1				
Detector:		Peak for pre-scan (120kHz resolution bandwidth)				
		Quasi-Peak and Average if maximum peak within 6dB of limit				
5.2.1 E.U.T. Operation						
Operating Environment:						
Temperature:	16.7 °C	Humidity:	59% RH	Atmospheric Pressure:	102	Kpa
EUT Operation:	1					
5.2.2 Test Specification						
The EUT was placed on a wooden table which is 0.8m in height. A non-metallic slide groove 6m long was placed at the same height for movement of the absorbing clamp. Absorbing clamp moved along the slide groove during testing to find the maximum disturbance reading. All reflecting or absorbing objects are not closer than 0.8m to the measuring set-up.						

Associated with the radiated emission test data in this report is a ±3.44dB measurement uncertainty.



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5.2.3 Measurement Data
An initial pre-scan was performed on the live and neutral lines.
Quasi-peak or average measurements were performed at the frequency which maximum peak emissions were detected.
Please refer to the attached quasi-peak & average measurement data.

Power Line									
Frequency (MHz)	Factor (dB)	Quasi-peak				Average			
		Reading Level (dBuV)	Measure Level (dBuV)	Limit (dBuV)	Margin (dB)	Reading Level (dBuV)	Measure Level (dBuV)	Limit (dBuV)	Margin (dB)
0.242	10.163	39.200	49.363	63.371	-14.008	28.900	39.065	51.486	-11.550
0.307	10.235	36.300	46.535	61.514	-14.979	29.700	39.936	51.486	-11.550
0.439	10.324	34.000	44.324	57.743	-13.419	30.100	40.425	47.686	-7.261
* 0.573	10.382	32.800	43.182	56.000	-12.818	29.400	39.782	46.000	-6.218
1.849	10.540	32.700	43.240	56.000	-12.760	27.400	37.940	46.000	-8.060
5.659	10.680	27.300	37.980	60.000	-22.020	22.400	33.080	50.000	-16.920

AV Input Cable									
Frequency (MHz)	Factor (dB)	Quasi-peak				Average			
		Reading Level (dBuV)	Measure Level (dBuV)	Limit (dBuV)	Margin (dB)	Reading Level (dBuV)	Measure Level (dBuV)	Limit (dBuV)	Margin (dB)
0.242	10.163	39.200	49.363	63.371	-14.008	28.900	39.065	53.343	-14.278
0.307	10.235	36.300	46.535	61.514	-14.979	29.700	39.936	51.486	-11.550
0.439	10.324	34.000	44.324	57.743	-13.419	30.100	40.425	47.686	-7.261
* 0.573	10.382	32.800	43.182	56.000	-12.818	29.400	39.782	46.000	-6.218
1.849	10.540	32.700	43.240	56.000	-12.760	27.400	37.940	46.000	-8.060
5.659	10.680	27.300	37.980	60.000	-22.020	22.400	33.080	50.000	-16.920

Note: “*” means the worst case
Measurement Level = Reading Level + Factor
Factor = Clamp Factor + Cable Loss



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5.3 Harmonics

Frequency Range:	100Hz to 2kHz
Test Requirement:	EN 61000-3-2

5.3.1 E.U.T. Operation

Operating Environment:						
Temperature:	22°C	Humidity:	62% RH	Atmospheric Pressure:	102.0	Kpa
EUT Operation:	1					

5.3.2 Test specification

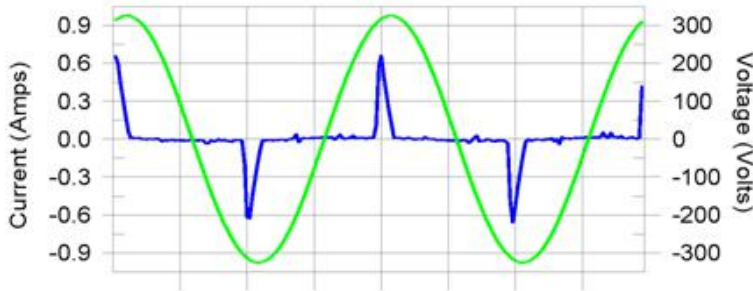
EUT operated in the mode as mentioned above, and connected to Harmonic/Flicker measuring equipment which was connected to an AC power source. Measurement was performed after EUT operating in static state for 10 seconds. Each order harmonics found to meet the relevant limits.



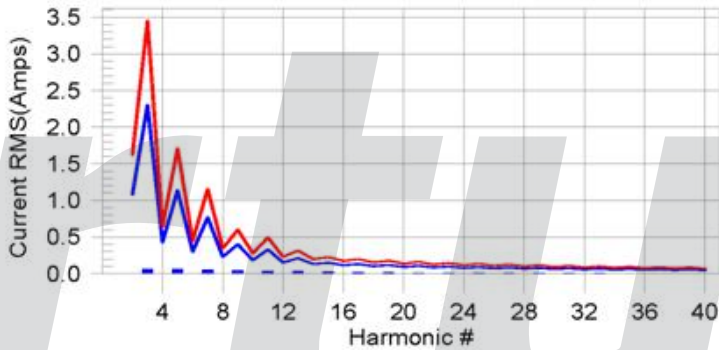
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5.3.3 Measurement Data

Test Result: Pass Source qualification: Normal
Current & voltage waveforms



Harmonics and Class A limit line European Limits



Test result: Pass Worst harmonic was #15 with 11.09% of the limit.



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Harm#	Harms(avg)	100%Limit	%of Limit	Harms(max)	150%Limit	%of Limit	Status
2	0.001	1.080	0.1	0.002	1.620	0.10	Pass
3	0.064	2.300	2.8	0.067	3.450	1.94	Pass
4	0.001	0.430	0.2	0.001	0.645	0.19	Pass
5	0.059	1.140	5.2	0.061	1.710	3.56	Pass
6	0.001	0.300	0.2	0.001	0.450	0.16	Pass
7	0.054	0.770	7.0	0.055	1.155	4.77	Pass
8	0.000	0.230	0.2	0.001	0.345	0.16	Pass
9	0.046	0.400	11.6	0.048	0.600	7.94	Pass
10	0.000	0.184	0.2	0.001	0.276	0.19	Pass
11	0.039	0.330	11.7	0.040	0.495	8.05	Pass
12	0.000	0.153	0.2	0.000	0.230	0.20	Pass
13	0.031	0.210	14.8	0.032	0.315	10.17	Pass
14	0.000	0.131	0.2	0.000	0.197	0.17	Pass
15	0.024	0.150	16.1	0.025	0.225	11.09	Pass
16	0.000	0.115	0.2	0.000	0.173	0.22	Pass
17	0.019	0.132	14.1	0.019	0.199	9.67	Pass
18	0.000	0.102	0.3	0.000	0.153	0.29	Pass
19	0.015	0.118	12.6	0.015	0.178	8.64	Pass
20	0.000	0.092	0.3	0.000	0.138	0.33	Pass
21	0.013	0.107	12.1	0.013	0.161	8.32	Pass
22	0.000	0.084	0.4	0.000	0.125	0.31	Pass
23	0.012	0.098	12.3	0.012	0.147	8.48	Pass
24	0.000	0.077	0.4	0.000	0.115	0.33	Pass
25	0.011	0.090	12.8	0.012	0.135	8.83	Pass
26	0.000	0.071	0.5	0.000	0.106	0.46	Pass
27	0.011	0.083	12.7	0.011	0.125	8.76	Pass
28	0.000	0.066	0.4	0.000	0.099	0.34	Pass
29	0.009	0.078	12.0	0.010	0.116	8.28	Pass
30	0.000	0.061	0.5	0.000	0.092	0.52	Pass
31	0.008	0.073	10.7	0.008	0.109	7.42	Pass
32	0.000	0.058	0.4	0.000	0.086	0.37	Pass
33	0.006	0.068	9.0	0.006	0.102	6.32	Pass
34	0.000	0.054	0.4	0.000	0.081	0.42	Pass
35	0.005	0.064	7.4	0.005	0.096	5.19	Pass
36	0.000	0.051	0.4	0.000	0.077	0.38	Pass
37	0.004	0.061	6.4	0.004	0.091	4.51	Pass
38	0.000	0.048	0.7	0.000	0.073	0.60	Pass
39	0.003	0.058	6.0	0.004	0.087	4.19	Pass
40	0.000	0.046	0.5	0.000	0.069	0.53	Pass



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Harm#	Harmonics V-rms	Limit V-rms	% of Limit	Status
2	0.367	0.460	79.67	OK
3	0.479	2.071	23.13	OK
4	0.146	0.460	31.79	OK
5	0.104	0.920	11.29	OK
6	0.078	0.460	16.99	OK
7	0.099	0.690	14.39	OK
8	0.070	0.460	15.18	OK
9	0.039	0.460	8.51	OK
10	0.060	0.460	13.02	OK
11	0.076	0.230	33.25	OK
12	0.050	0.230	21.52	OK
13	0.031	0.230	13.51	OK
14	0.040	0.230	17.38	OK
15	0.044	0.230	19.05	OK
16	0.040	0.230	17.50	OK
17	0.040	0.230	17.49	OK
18	0.043	0.230	18.62	OK
19	0.019	0.230	8.39	OK
20	0.032	0.230	14.01	OK
21	0.036	0.230	15.78	OK
22	0.027	0.230	11.61	OK
23	0.022	0.230	9.58	OK
24	0.024	0.230	10.48	OK
25	0.029	0.230	12.81	OK
26	0.023	0.230	10.19	OK
27	0.027	0.230	11.71	OK
28	0.023	0.230	9.84	OK
29	0.017	0.230	7.28	OK
30	0.023	0.230	9.90	OK
31	0.030	0.230	13.03	OK
32	0.019	0.230	8.46	OK
33	0.014	0.230	6.21	OK
34	0.019	0.230	8.11	OK
35	0.020	0.230	8.54	OK
36	0.017	0.230	7.43	OK
37	0.020	0.230	8.55	OK
38	0.016	0.230	6.86	OK
39	0.015	0.230	6.65	OK
40	0.017	0.230	7.44	OK



Shenzhen JT Detection Technology Co., Ltd

5.4 Voltage changes, voltage fluctuations and flicker

Test Requirement:		EN 61000-3-3				
5.4.1 E.U.T. Operation						
Operating Environment:						
Temperature:	22°C	Humidity:	62% RH	Atmospheric Pressure:	102.0	Kpa
EUT Operation:	Connect EUT output to dummy load.					
5.4.2 Test specification						
EUT was operated in the mode as mentioned above, and connected to Harmonic/Flicker measuring equipment which was connected to an AC power source.						



Shenzhen JT Detection Technology Co., Ltd

5.4.3 Measurement Data





Shenzhen JT Detection Technology Co., Ltd

6 Immunity Test Results

6.1 Electrostatic discharge immunity test

Acceptable Performance Criterion:	B
Discharge Impedance:	330 Ω / 150 pF
Discharge Voltage:	Air Discharge: ±8 kV
	Contact Discharge: ±4 kV
	VCP, HCP: ±4 kV
Polarity:	Positive & Negative
Minimum discharge Interval:	1 second

6.1.1 E.U.T. Operation

Operating Environment:						
Temperature:	22°C	Humidity:	52% RH	Atmospheric Pressure:	102.0	Kpa
EUT Operation:	1					

6.1.2 Test specification

EUT was operated in the mode as mentioned above,. Both contact and air discharge was executed. contact discharge to the conductive surfaces and to coupling planes; air discharge at insulating surfaces. Each test point shall be subjected to 10 discharges at least (For each Level and polarity).



Shenzhen JT Detection Technology Co., Ltd

6.1.3 Measurement Data

Test Record

Form: AMC 410-6

Electrostatic Discharge Immunity Test Results				
Applicant: <u>Shenzhen Chuang Cheng Da Electronic Technology Co., Ltd.</u>			Test Date: <u>Mar 09, 2020</u>	
EUT: <u>infrared radiation thermometer</u>			Test Result: <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
M/N: <u>JJT889</u>			Temp: <u>25</u> °C , Humi: <u>55</u> %	
Power Supply: <u>3V</u>			Atmospheric Pressure: <u>102.0</u> Kpa	
Operating Mode	Running mode			Criterion
Test Level	Air Discharge(A) <u>±8</u> KV , Contact Discharge (C) <u>±4</u> KV			B
Test Position	Discharge Mode	Points	Discharge times for each Point (for each Level And polarity)	Result
EUT enclosure	A	4	10	Pass
Slot	A	4	10	Pass
HCP	C	4	10	Pass
VCP	C	4	10	Pass
Note: "A" means Air Discharge, "C" means Contact Discharge, Horizontal Coupling Plane(HCP) and Vertical Coupling plane(VCP).				



Shenzhen JT Detection Technology Co., Ltd

6.2RF field strength immunity test

Acceptable Performance Criterion:	A
Test Level	3 V/m
Test Distance	3 m
Frequency Range	80MHz~1000MHz
Polarity:	Horizontal & Vertical

6.2.1 E.U.T. Operation

Operating Environment:						
Temperature:	25℃	Humidity:	60% RH	Atmospheric Pressure:	102.0	Kpa
EUT Operation:	Connect EUT output to dummy load.					

6.2.2 Test specification

Test was executed in a fully Anechoic chamber. An antenna was used to transmit interference signal. EUT was placed upon a wooden table above the reference ground 0.8m, and was positioned so that the four sides of the EUT shall be exposed to the electromagnetic field in a sequence, In each position the performance of the EUT was investigated. A camera was used to monitor the loss of function or degradation of performance of the EUT.

This test item was transferred to Shenzhen Academy of Metrology and Quality Inspection (SMQ) which was confirmed to have enough capacity to perform this subcontract work.



Shenzhen JT Detection Technology Co., Ltd

6.2.3 Measurement Data

Test Record

Form: AMC410-7

Radiated Frequency Field Strength Immunity Test Results				
Applicant: Shenzhen Chuang Cheng Da Electronic Technology Co., Ltd.			Test Date: Mar 09, 2020	
EUT: infrared radiation thermometer			Test Result: <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
M/N: JJT889			Temp: 25 °C , Humi: 55 %	
Power Supply: 3V			Atmospheric Pressure: 102.0 Kpa	
Test Port	Enclosure			
Operating Mode	Running mode			
Test Level	3 V/m (r.m.s) (unmodulated)			Criterion A
Frequency Range(MHz)	Antenna polarity	Modulation	EUT position	Result
80~1000	Horizontal	1kHz, 80%, AM	Front	Pass
			Rear	Pass
			Left	Pass
			Right	Pass
80~1000	Vertical	1kHz, 80%, AM	Front	Pass
			Rear	Pass
			Left	Pass
			Right	Pass
Note : None				



Shenzhen JT Detection Technology Co., Ltd

6.3Electrical fast transient/burst immunity test

Acceptable Performance Criterion:	B
Test Level:	0.5, 1.0, kV on AC Line; 0.5 kV on Signal Line
Repetition Frequency:	5 kHz
Burst Duration:	300 ms
Test Duration:	2 minute for each level & polarity

6.3.1 E.U.T. Operation

Operating Environment:						
Temperature:	22°C	Humidity:	62% RH	Atmospheric Pressure:	102.0	Kpa
EUT Operation:	Connect EUT output to dummy load.					

6.3.2 Test specification

EUT was placed on a metal ground reference plane and was insulated from it by a wooden support which is 0.1m thick. The ground reference plane is connected to the IU-DQX08tective earth. The test generator and the coupling/decoupling network were placed directly on, and bonded to the ground reference plane.



Shenzhen JT Detection Technology Co., Ltd

6.3.3 Measurement Data

Test Record

Form: AMC 410-8

Electrical Fast Transient/Burst Test Results			
Applicant:Shenzhen Chuang Cheng Da Electronic Technology Co., Ltd.		Test Date: Mar 09,2020	
EUT: infrared radiation thermometer		Test Result: <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
M/N: JJT889		Temp: 25 °C , Humi: 55 %	
Power Supply: 3V		Atmospheric Pressure: 102.0 Kpa	
Operating Mode	Running mode		Criterion
Test Signal	5/50ns, repetition frequency : <input checked="" type="checkbox"/> 5KHz / <input type="checkbox"/> 100 KHz		B
Coupling Line	Test Level (KV)	Test Duration (S)	Result
L	1	120	Pass
N	1	120	Pass
PE	N/A	N/A	N/A
L+N	1	120	Pass
L+PE	N/A	N/A	N/A
N+PE	N/A	N/A	N/A
L+N+PE	N/A	N/A	N/A
DC/Signal/control Line	N/A	N/A	N/A



Shenzhen JT Detection Technology Co., Ltd

Note: None

6.4 Surge immunity test

Acceptable Performance Criterion:	B
Test Level:	0.5, 1kV Live to Neutral
	0.5, 1, 2kV Live, Neutral to Earth
Polarity:	Positive & Negative
Generator source impedance:	2 Ω & 12 Ω
Trigger Mode:	Internal
No. of surges:	5 positive, 5 negative at 0°, 90°, 180°, 270°.

6.4.1 E.U.T. Operation

Operating Environment:

Temperature:	22°C	Humidity:	62% RH	Atmospheric Pressure:	102.0	Kpa
--------------	------	-----------	--------	-----------------------	-------	-----

EUT Operation: Connect EUT output to dummy load.

6.4.2 Test specification

EUT was placed on a wooden table which is 0.8m above the ground and operated in the mode as mentioned above,. The power cord between the EUT and the coupling/decoupling network was bundled so as to make it less than 2 m in length.



Shenzhen JT Detection Technology Co., Ltd

6.4.3 Measurement Data**Test Record**

Form: AMC 410-9

Surge Immunity Test Results

Applicant: Shenzhen Chuang Cheng Da Electronic Technology Co., Ltd.

Test Date: Mar 09, 2020

EUT: infrared radiation thermometer

Test Result: ☒ Pass ☐ Fail

M/N: JJT889

Temp: 25 °C, Humi: 55 %

Power Supply: 3V

Atmospheric Pressure: 102.0 Kpa

Operating Mode	Running mode			Criterion	B
Test Port	AC Input port				
Test Signal	■1.2/50 μs □10/700μs				
Coupling Line	Test Level (KV)	Phase	Pulse	Interval (s)	Result
L-N	1	0°~270°	10	60	Pass
L-PE	N/A	N/A	N/A	N/A	N/A
N-PE	N/A	N/A	N/A	N/A	N/A
Signal Line	N/A	N/A	N/A	N/A	N/A

Note: None



Shenzhen JT Detection Technology Co., Ltd

6.5 Conducted disturbance immunity Test

Acceptable Performance Criterion:	A
Test Level	3 V
Frequency Range	0.150MHz~80MHz

6.5.1 E.U.T. Operation

Operating Environment:						
Temperature:	25°C	Humidity:	60% RH	Atmospheric Pressure:	102	Kpa
EUT Operation:	Connect EUT output to dummy load.					

6.5.2 Test specification

The equipment to be tested was placed on an insulating support of 0,1 m height above a ground reference Plane. The minimum distance between the EUT and all other conductive structures, except the ground reference plane is more than 0,5 m. All relevant cables were IU-DQX08vided with the aplIU-DQX08priate coupling and decoupling devices at a distance between 0,1 m and 0,3 m from the IU-DQX08jected geometry of the EUT .

This test item was transferred to Shenzhen Academy of Metrology and Quality Inspection (SMQ) which was confirmed to have enough capacity to perform this subcontract work.



Shenzhen JT Detection Technology Co., Ltd

6.5.3 Measurement Data

Test Record

Form: AMC 410-10

Conducted Disturbance Immunity Test Results					
Applicant:Shenzhen Chuang Cheng Da Electronic Technology Co., Ltd.			Test Date: Mar 09,2020		
EUT: infrared radiation thermometer			Test Result: <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail		
M/N: JJT889			Temp: 25 °C , Humi: 55 %		
Power Supply: 3V			Atmospheric Pressure: 102.0 Kpa		
Test Port	AC Input Port				
Operating Mode	Running mode				
Test Level (V)	3 V(r.m.f) (unmodulated)				Criterion A
Step Size	1 %	Dwell Time (S)	0.5		
Frequency Range (MHz)	Modulation		Result		
0.15~80	1k Hz, 80%, AM		Pass		
N/A	N/A		N/A		
Note: None.					



Shenzhen JT Detection Technology Co., Ltd

6.6 Power frequency magnetic field immunity test

Acceptable Performance Criterion:	A
Test Level:	1 A/m
Coil Orientation:	X & Y & Z
Test Duration:	5 Minutes for each orientation

6.6.1 E.U.T. Operation

Operating Environment:						
Temperature:	22°C	Humidity:	62% RH	Atmospheric Pressure:	102.0	Kpa
EUT Operation:	Connect EUT output to dummy load.					

6.6.2 Test specification

The equipment is configured and connected to satisfy its functional requirements. It was placed on the ground reference plane with the interposition of a 0,1 m thickness wooden support and was placed in the center of the induction coil.. All cables (include power cord and signal line) were exposed to the magnetic field for at least 1m of their length.



Shenzhen JT Detection Technology Co., Ltd

6.6.3 Measurement Data**Test Record**

Form: AMC 410-14

Power Frequency Magnetic Field Immunity Test Results

Applicant: Shenzhen Chuang Cheng Da Electronic Technology Co., Ltd.

Test Date: Mar 09, 2020

EUT: infrared radiation thermometer

Test Result: ☒ Pass ☐ Fail

M/N: JJT889

Temp: 25 °C , Humi: 55 %

Power Supply: 3V

Atmospheric Pressure: 102.0 Kpa

Operating Mode	Running mode			
Test Level	Test Duration	Coil Orientation	Criterion	Result
1 A/m	5 minus	X	A	Pass
1 A/m	5 minus	Y	A	Pass
1 A/m	5 minus	Z	A	Pass

Notes: None



Shenzhen JT Detection Technology Co., Ltd

6.7 Voltage dips and interruptions immunity test

Acceptable Performance Criterion:	B & C
Test Level:	<5% of U _T (Supply Voltage) for 0.5 and 250 Periods
	70 % of U _T (Supply Voltage) for 25 Periods
No. of Dips / Interruptions:	3 per Level

6.7.1 E.U.T. Operation

Operating Environment:						
Temperature:	22°C	Humidity:	62% RH	Atmospheric Pressure:	102.0	Kpa

EUT Operation: Connect EUT output to dummy load.

6.7.2 Test specification

EUT connected to the test generator with the shortest power supply cable as specified by the EUT manufacturer. The rated voltage of the EUT was used as the basis for voltage test level specification. After each group of tests, a full functional check was performed.



Shenzhen JT Detection Technology Co., Ltd

6.7.3 Measurement Data

Test Record

Form: AMC 410-11

Voltage Dips And Interruptions Test Results					
Applicant: Shenzhen Chuang Cheng Da Electronic Technology Co., Ltd.			Test Date: Mar 09, 2020		
EUT: infrared radiation thermometer			Test Result: <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail		
M/N: JJT889			Temp: 25 °C , Humi: 55 %		
Power Supply: 3V			Atmospheric Pressure: 102.0 Kpa		
Test Port	AC Input				
Operating Mode	Running mode				
Level (%U _T)	Interruption & Dips (%U _T)	Duration (Cyc)	Phase	Criterion	Result
<5	>95	0.5	0°	B	Pass
70	30	25	0°	C	Pass
<5	>95	250	0°	C	Pass
Note: None.					



Shenzhen JT Detection Technology Co., Ltd

7 APPENDIX-Photographs Of EUT Constructional Detail

Appearance photo



--End of report--



TMC Testing Services (Shenzhen) Co., Ltd

Report No.: TMC200326114-E



APPLICATION FOR EMC DIRECTIVE

On Behalf of

HuNan KEG Electronic Technology Co., Ltd

non-contact infrared medical thermometer

Trade Name: hanjindian

Model: HD-E-01

Prepared For : HuNan KEG Electronic Technology Co., Ltd

Floor 3, standard workshop, Fuyuan company, export processing zone, bailutang Town, Suxian District, Chenzhou City, Hunan Province, China

Prepared By : TMC Testing Services (Shenzhen) Co., Ltd.

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Tel: +86-755- 86642861

Web: www.tmc-lab.com

E-mail: Cert@tmc-lab.com

Date of Test : March 27, 2020-March 28, 2020

Date of Report : March 30, 2020

Report Number : TMC200326114-E

TMC Testing Services (Shenzhen) Co., Ltd
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TMC Testing Services (Shenzhen) Co., Ltd

Report No.: TMC200326114-E

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TMC Testing Services (Shenzhen) Co., Ltd

Report No.: TMC200326114-E

TEST REPORT DECLARATION

Applicant	HuNan KEG Electronic Technology Co., Ltd
Address	Floor 3, standard workshop, Fuyuan company, export processing zone, bailutang Town, Suxian District, Chenzhou City, Hunan Province, China
EUT Description	non-contact infrared medical thermometer
Manufacturer	HuNan KEG Electronic Technology Co., Ltd
Address	Floor 3, standard workshop, Fuyuan company, export processing zone, bailutang Town, Suxian District, Chenzhou City, Hunan Province, China
Model Number	HD-E-01

Test Standards:

FCC Part 15 B: 2017

The EUT described above is tested by US to determine the maximum emission levels emanating from the EUT, the maximum emission levels are compared to the FCC Part 15 Subpart Class B limits. The measurement results are contained in this test report and TMC Testing Services (Shenzhen) Co., Ltd is assumed of full responsibility for the accuracy and completeness of these measurements. Also, this report shows that the EUT is to be technically compliant with the FCC requirements.

This report applies to above tested sample only and shall not be reproduced in part without written approval of TMC Testing Services (Shenzhen) Co., Ltd

Prepared by:

Nina Wu

Nina Wu/Assistant

Reviewer:

Vivian Jiang

Vivian Jiang/Supervisor

Approved & Authorized Signer:

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TMC Testing Services (Shenzhen) Co., Ltd

Report No.: TMC200326114-E

1. GENERAL INFORMATION

1.1. Report information

1.1.1. This report is not a certificate of quality; it only applies to the sample of the specific product/equipment given at the time of its testing. The results are not used to indicate or imply that they are application to the similar items. In addition, such results must not be used to indicate or imply that TMC approves recommends or endorses the manufacture, supplier or use of such product/equipment, or that TMC in any way guarantees the later performance of the product/equipment.

1.1.2. The sample/s mentioned in this report is/are supplied by Applicant, TMC therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture or any information supplied.

1.1.3. Additional copies of the report are available to the Applicant at an additional fee. No third part can obtain a copy of this report through TMC, unless the applicant has authorized TMC in writing to do so.

1.2. Measurement Uncertainty

Available upon request.

1.3. Test Uncertainty

Conducted Emission Uncertainty = $\pm 2.66\text{dB}$

Radiated Emission Uncertainty = $\pm 4.26\text{dB}$

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TMC Testing Services (Shenzhen) Co., Ltd

Report No.: TMC200326114-E

2. PRODUCT DESCRIPTION

2.1. EUT Description

Description	:	non-contact infrared medical thermometer
Applicant	:	HuNan KEG Electronic Technology Co., Ltd Floor 3, standard workshop, Fuyuan company, export processing zone, bailutang Town, Suxian District, Chenzhou City, Hunan Province, China
Manufacturer	:	HuNan KEG Electronic Technology Co., Ltd Floor 3, standard workshop, Fuyuan company, export processing zone, bailutang Town, Suxian District, Chenzhou City, Hunan Province, China
Model Number	:	HD-E-01

2.2. Test Conditions

Temperature: 23~25°C

Relative Humidity: 55~63 %

2.3. Support Equipment List

No.	Equipment	Model No.	Serial No.	FCC ID	Trade Name	Data Cable	Power Cord

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Report No.: TMC200326114-E

3. TEST RESULTS SUMMARY

Table 1 Test Results Summary

Test Items	Test Results
Conducted disturbance	N/A
Radiated disturbance	Pass



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Report No.: TMC200326114-E

4. TEST EQUIPMENT USED

4.1.For Conducted Emission Test

Item	Equipment	Manufacturer	Model No.	Serial No.	Last Cal.	Cal. Interval
1.	Test Receiver	Rohde & Schwarz	ESH30	828985/018	Jun 01,2019	1 Year
2.	Pulse Limiter	Rohde & Schwarz	ESH3-Z2	100006	Jun 01,2019	1 Year
3.	L.I.S.N.	Rohde & Schwarz	ESH2-Z5	834549/005	Jun 01,2019	1 Year
4.	Conical	Emtek	N/A	N/A	N/A	N/A
5.	Voltage Probe	Schwarzbeck	TK9416	N/A	Jun 01,2019	1 Year
6.	Coaxial Switch	Anritsu	MP59B	6100214550	Jun 01,2019	1 Year

4.2.For Radiated Emission Measurement

Anechoic Chamber

Item	Equipment	Manufacturer	Model No.	Serial No.	Last Cal.	Cal. Interval
1.	Spectrum Analyzer	ANRITSU	MS2661C	6200140915	Jun 01,2019	1 Year
2.	Test Receiver	Rohde&Schwarz	ESC830	828982/018	Jun 01,2019	1 Year
3.	Bilog Antenna	Schwarzbeck	VULB9163	142	Jun 01,2019	1 Year
4.	50 Coaxial Switch	Anritsu Corp	MP59B	6100237248	Jun 01,2019	1 Year
5.	Cable	Schwarzbeck	AK9513	ACRX1	Jun 01,2019	1 Year
6.	Cable	Rosenberger	N/A	FR2RX2	Jun 01,2019	1 Year
7.	Cable	Schwarzbeck	AK9513	CRRX2	Jun 01,2019	1 Year
8.	Cable	Schwarzbeck	AK9513	CRRX2	Jun 01,2019	1 Year
9.	Single Phase Power Line Filter	MPE	23332C	N/A	Jun 01,2019	1 Year
10.	Single Phase Power Line Filter	MPE	23333C	N/A	Jun 01,2019	1 Year
11.	Signal Generator	HP	864A	3625U00573	Jun 01,2019	1 Year

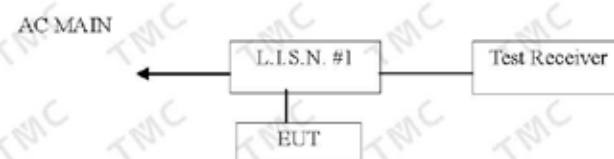


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Report No.: TMC200326114-E

5. CONDUCTED EMISSION TEST

5.1. Block Diagram of Test Setup



(EUT: non-contact infrared medical thermometer)

5.2. Test Standard

FCC Part 15 B:2017

5.3. Conducted Emission Limit (Class B)

Frequency MHz	Limits dB(μV)	
	Quasi-peak Level	Average Level
0.15 ~ 0.50	66 ~ 56*	56 ~ 46*
0.50 ~ 5.00	56	46
5.00 ~ 30.00	60	50

Notes: 1. *Decreasing linearly with logarithm of frequency.

5.4. EUT Configuration on Test

The following equipments are installed on conducted emission test to meet Part 15 requirement and operating in a manner, which tends to maximize its emission characteristics in a normal application.

5.4.1. EUT Information

Model Number: HD-E-01

5.5. Operating Condition of EUT

- 5.5.1. Setup the EUT and simulators as shown in Section 5.1.
- 5.5.2. Turn on the power of all equipments.
- 5.5.3. Let the EUT work in test modes (EUT Working) and test it.

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Report No.: TMC200326114-E

5.6. Test Procedure

The EUT is put on a table of non-conducting material that is 80cm high. The vertical conducting wall of shielding is located 40cm to the rear of the EUT. The power line of the EUT is connected to the AC mains through a Artificial Mains Network (A.M.N.). A EMI test receiver (R&S Test Receiver ESCS30) is used to test the emissions form both sides of AC line. The bandwidth of EMI test receiver is set at 9kHz.

The bandwidth of the test receiver (R&S Test Receiver ESHS30) is set at 10KHz. All the test results are listed in Section 5.7.

5.7. Test Result

N/A

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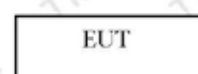
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6. RADIATED EMISSION MEASUREMENT

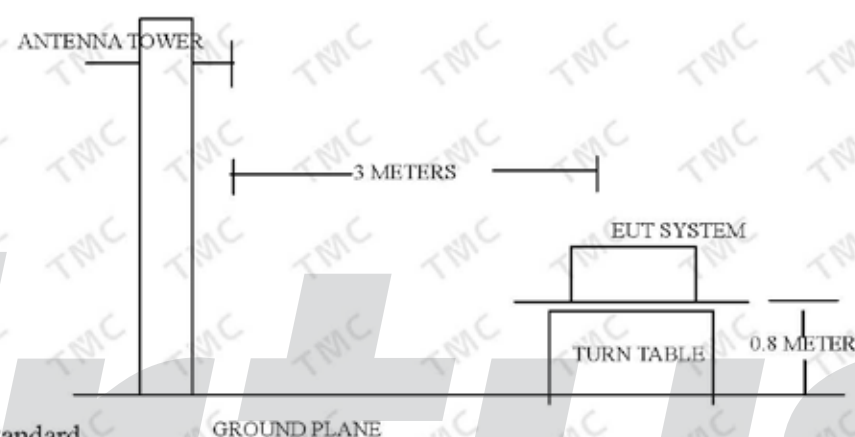
6.1. Block Diagram of EUT Configuration

6.1.1. Block Diagram of connection between the EUT and the simulators



(EUT: non-contact infrared medical thermometer)

6.1.2. Anechoic Chamber Test Setup Diagram



6.2. Test Standard

FCC Part 15 B:2017

6.3. Radiated Emission Limit (Class B)

FREQUENCY (MHz)	DISTANCE (Meters)	FIELD STRENGTHS LIMITS (dBμV/m)
30 ~ 88	3	40.0
88 ~ 216	3	43.5
216 ~ 960	3	46.0
960 ~ 1000	3	54.0

Note: (1) The smaller limit shall apply at the edge between two frequency bands.

(2) Distance refers to the distance in meters between the measuring instrument antenna and the closed point of any part of the EUT or system.

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6.4. EUT Configuration on Test

The following equipment are installed on Radiated Emission Measurement to meet the Commission requirements and operating regulations in a manner which tends to maximize its emission characteristics in normal application.

6.5. Operating Condition of EUT

6.5.1. Setup the EUT as shown on Section 6.1.2

6.5.2. Turn on the power of all equipments.

6.5.3. Let the EUT work in test mode (EUT working) and measure it.

6.6. Test Procedure

The EUT is placed on a turn table which is 0.8 meter above ground. The turn table can rotate 360 degrees to determine the position of the maximum emission level. The EUT is set 3 meters away from the receiving antenna which is mounted on a antenna tower. The antenna can move up and down between 1 to 4 meters to find out the maximum emission level. Broadband antenna (calibrated by dipole antenna) are used as a receiving antenna. Both horizontal and vertical polarization of the antenna are set on measurement.

The bandwidth setting on the test receiver (R&S TEST RECEIVER ESCS20) is 120 KHz. The EUT is tested in Anechoic Chamber. The frequency range from 30MHz to 1000 MHz is checked. All the test results are listed in Section 6.7. and all the scanning waveform are attached within **Appendix I**

6.7. Test Result

PASS

Test Mode: operating

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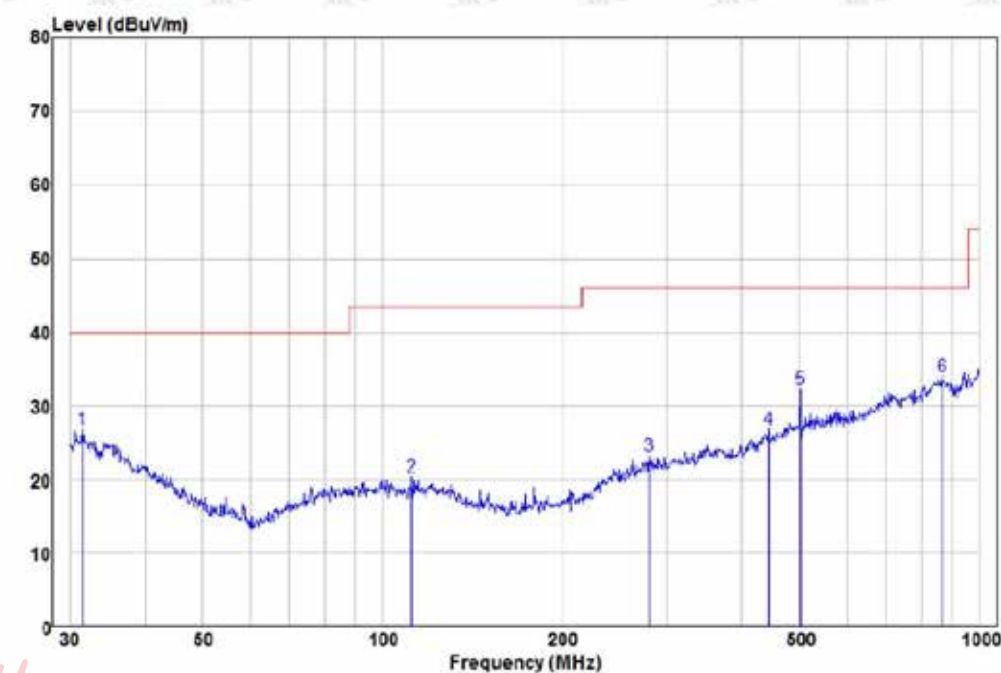
APPENDIX I

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Condition : FCC PART15B CLASS B VERTICAL

Condition	Freq	Read Level	Adm150 Factor	Class B Level	Limit Line	Over Limit	Remark	Pol/Phase
	MHz	dBuV	dB/m	dBuV/m	dBuV/m	dB		
1	31.40	11.21	15.55	26.75	40.00	-13.24	Peak	VERTICAL
2	112.13	9.97	10.29	20.25	43.50	-23.24	Peak	VERTICAL
3	280.02	10.20	13.07	23.27	46.00	-22.73	Peak	VERTICAL
4	443.29	10.20	16.52	26.72	46.00	-19.28	Peak	VERTICAL
5	501.18	14.03	18.29	32.32	46.00	-13.68	Peak	VERTICAL
6 pp	869.13	9.99	23.97	33.95	46.00	-12.04	Peak	VERTICAL

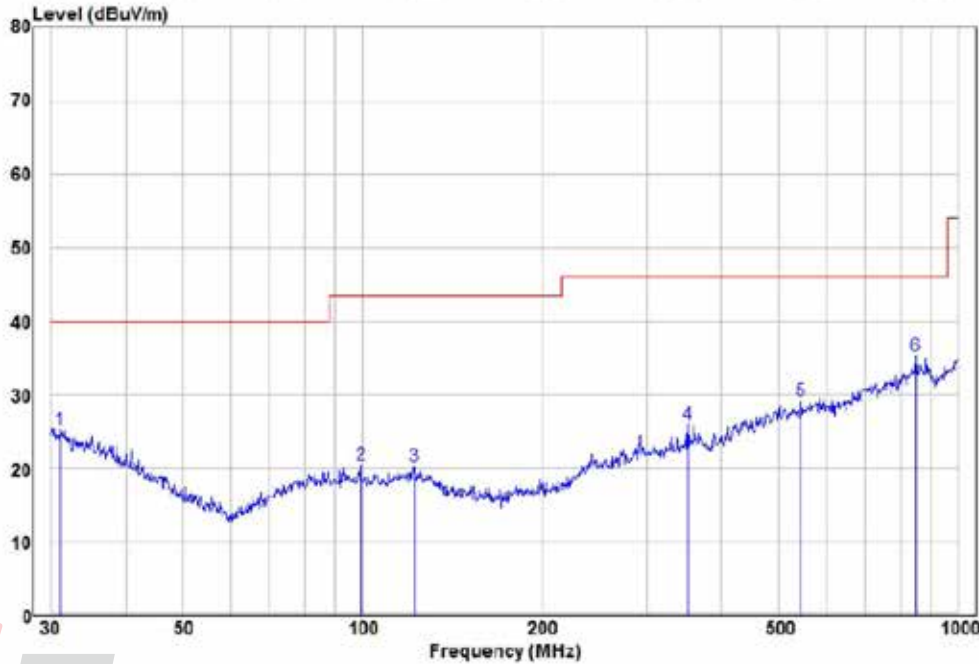
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Condition : FCC PART15B CLASS B HORIZONTAL

		Read		Limit	Over		
	Freq	Level	Factor	Level	Line	Limit	Remark
	MHz	dBuV	dB/m	dBuV/m	dBuV/m	dB	
1	31.07	9.70	15.63	25.33	40.00	-14.67	Peak
2	99.53	9.84	10.62	20.46	43.50	-23.04	Peak
3	121.98	9.62	10.62	20.24	43.50	-23.26	Peak
4	351.71	10.95	14.99	25.94	46.00	-20.06	Peak
5	545.18	10.41	18.75	29.16	46.00	-16.84	Peak
6 pp	848.06	11.26	24.06	35.32	46.00	-10.68	Peak



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APPENDIX II



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Photo 1 Radiated Emission Test



Photo 2 General Appearance of the EUT



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Photo 3 General Appearance of the EUT



Photo 4 General Appearance of the EUT





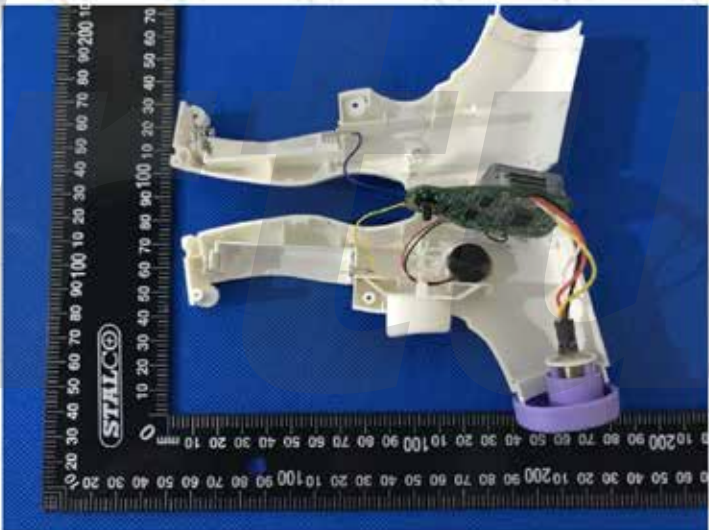
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Photo 5 General Appearance of the EUT



Photo 6 General Appearance of the EUT



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Photo 7 General Appearance of the EUT

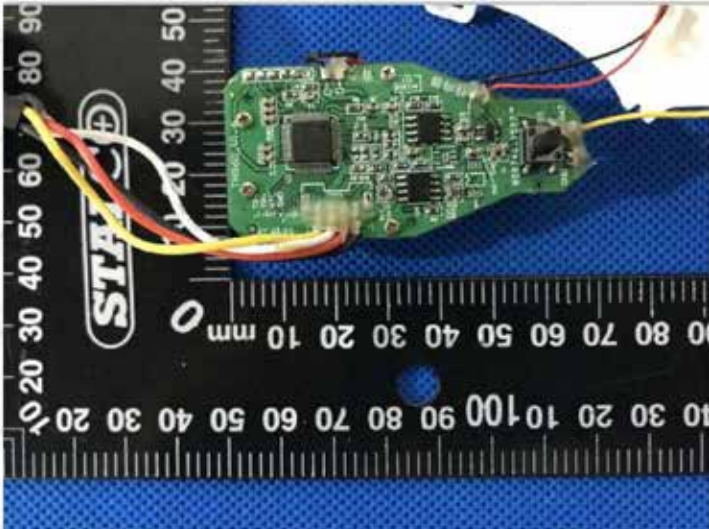
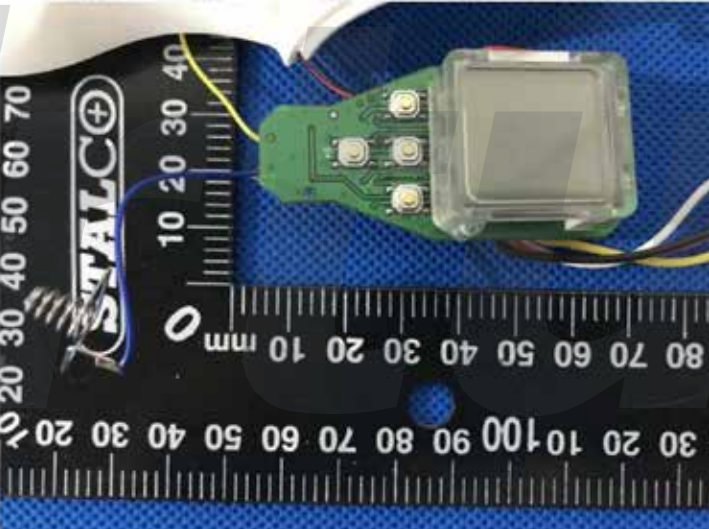


Photo 8 General Appearance of the EUT



****END OF REPORT****



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