

A grayscale background image showing various medical supplies. In the top right, there is a black rubber bulb connected to a clear plastic tube. Below it, a surgical mask is partially visible. In the bottom right, there are two syringes and another surgical mask. The central part of the image is a large white rectangle containing the title and subtitle.

Personal Protective Equipment

PPE Brochure

Protective Face Shield



SPECIFICATIONS

Transmittance 92%

Size 33 x 19cm

Material 0.18mm Clear PET + foam + elastic band

Packaging Details 10pcs / bag 200pcs / carton

CHARACTERISTICS

Effective protection against dust, anti fog, splash protection, comfortable

Disposable 3ply Mask



SPECIFICATIONS

Outer Layer - Spun-bonded fabric

Filter Layer - Melt blown fabric

Inner Layer - Spun-bonded fabric

Nose Clip - PO/PE

Elastic Band - Polyurethane

Colour

Mask - Blue/White, Elastic Band - White, Nose Clip Style - Flat nose clip

DIMENSIONS

Body Size 17.5 x 9.5cm Nose Clip 9.5cm Earband 17cm

Disposable Gown CPE



SPECIFICATIONS

Material 100% Cast Polyethylene (CPE)

Size *S: 110-130cm *M: 115-137cm *L: 120-140cm *XL: 125-145cm *XXL: 130-150cm *XXXL: 135-158cm

Colour - White / Blue

Density - 35g/pc

CERTIFICATE - ISO13485/CE

Smooth, embossed surface, thumb loop, elastic

FEATURES

Designed to maximise comfort, available in both open back and full coverage, breathable and fluid resistant, breakaway design for easy removal.

Disposable Gown PP



SPECIFICATIONS

Material Polyethylene nonwovens

Size *S: 110-130cm *M: 115-137cm *L: 120-140cm *XL: 125-145cm *XXL: 130-150cm *XXXL: 135-158cm

Colour - Dark Blue / Blue / Green

Density - 35gsm

CERTIFICATE - ISO13485/CE

Smooth, embossed surface, thumb loop, elastic

FEATURES

Designed to maximise comfort, available in both open back and full coverage, breathable and fluid resistant, breakaway design for easy removal.

Disposable Gown SMS



SPECIFICATIONS

Material SMS (Spunbound, meltblown, spunbond)

Size *S: 110-130cm *M: 115-137cm *L: 120-140cm *XL: 125-145cm *XXL: 130-150cm *XXXL: 135-158cm

Colour - Dark Blue / Blue / Green

Density - 40gsm

CERTIFICATE - ISO13485/CE

FEATURES

Low linting, abrasion resistant, breathable and fluid resistant, antistatic treatment, lightweight, breathable and impervious, breakaway design for easy removal.

FFP3D Medical Mask



SPECIFICATIONS

Particulate Respirator 8835

This filtering face piece respirator meets the requirements of EN149:2001 category FFP3D and should be used to protect the wearer from solid and non-volatile liquid particles only.

The respirator can be used in concentrations of contaminant up to 20 times the Occupational Exposure Limit.

CERTIFICATE - IFA/1901182

Sterile ICU Suit



SPECIFICATIONS

Material PP + SMS

Size - S, M, L, XL, XXL

Colour - White

Density - 230g

Shoe Covers



SPECIFICATIONS

Material Non sterlised PP + SMS

Size - M, L, XL

Colour - White

Density - 60gsm

Non Sterilised Nitrile



SPECIFICATIONS

Material Nitrile

Size - 6.0 / 6.5 / 7.0 / 7.5 / 8.0 / 8.5

Colour - White / Blue

Density - 3.0g

Non Sterilised Vinyl



SPECIFICATIONS

Material Non sterilised vinyl

Size - 6.0 / 6.5 / 7.0 / 7.5 / 8.0 / 8.5

Colour - White

Density - 4.0g

Sterilised Surgical



SPECIFICATIONS

Material EN445 Latex

Size - One Size

Colour - White

Density - 22g

812A Transport Ventilator



SPECIFICATIONS

CWH 3010 Ventilator



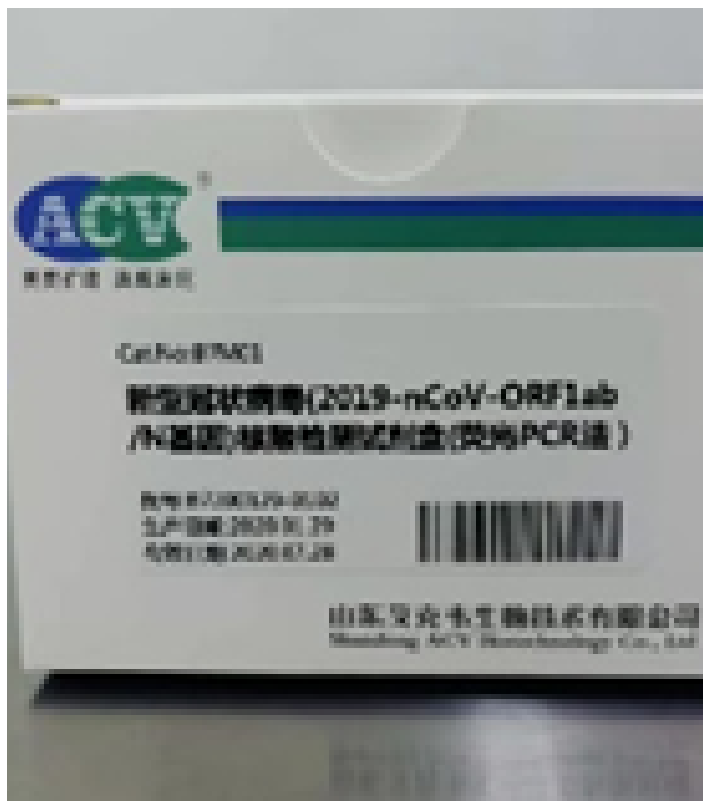
SPECIFICATIONS

TNI Soft Flow Ventilator



SPECIFICATIONS

PCR Test Kit



SPECIFICATIONS

FFP2 Disposable Mask



SPECIFICATIONS

Outer Layer - Needle punched cotton

Filter Layer - Melt blown fabric

Inner Layer - Needle punched cotton

Elastic Band - Polyurethane

Colour

Mask - White

DIMENSIONS

Body Size 130 x 125 x 68mm Nose Clip 68mm Earband 170mm

Polythene Apron



SPECIFICATIONS

Colours - White / Yellow / Blue / Green / Red / Clear / Pink

686 x 1170mm 16 micron unisex disposable

Perforated on a roll

Tolerance - +/-25%

Impact Strength - $\geq 80\text{g}$

10% minimum opacity

Body Bag PEVA



SPECIFICATIONS

Body Bag PEVA

Adult size 220 x 107cm

White with 3 sided zip

Capacity 140kg = 22 stone

Chlorine Tablets and Granules



SPECIFICATIONS

Appendix

Documentation 1

certificate no. IFA 1901182 dated 2019-07-09		 IFA Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung Prüf- und Zertifizierungsstelle im DGUV Test
<u>Translation</u> In any case, the German original shall prevail.		European notified body Identification number: 0121
EU Type-Examination Certificate		
Name and address of the manufacturer:	YANGXI VENUS PPE MANUFACTURE LTD. No. 23 Xincheng Industrial Zone, Yangxi county Yangjiang city, Guangdong PEOPLE'S REPUBLIC OF CHINA	
Product designation:	VIC823V FFP3 NR D EN 149:2001+A1:2009	
Type:	Particle filtering half mask with exhalation valve	
Testing based on:	DIN EN 149:2009	
Corresponding report:	201920901/2120 of 2019-07-05 - IFA, Sankt Augustin	
Further details:	For protection against non highly volatile liquid and solid particles. Class of device: FFP3 NR D Maximum application time or particle exposure one single shift. This document is valid in connection with the technical file and the instructions for use in English language, both provided with IFA endorsement 1901182 of 2019-07-05.	
The product mentioned above is a personal protective equipment of category III in accordance with the regulation (EU) 2016/425. This EU type-examination certificate may only be used in conjunction with corresponding control measures according to Module C2 (Annex VII) or Module D (Annex VIII). The product tested complies with the essential requirements of Annex II. The present certificate is valid until and including: 2024-07-08 Further provisions concerning the validity, the extension of the validity and other conditions are laid down in the Rules of Procedure for Testing and Certification.		
 Dr. rer. nat. Peter Paszkiewicz Head of testing and certification body		 B. Sc. Maria Schwan Certification officer
PD001_Kart 03-2.18		 DAKkS Deutsche Akkreditierungsstelle D-20-17009-33-00
Deutsche Gesetzliche Unfallversicherung (DGUV) e.V. Spitzenverband der gewerblichen Berufsgenossenschaften und der Unfallversicherungsträger der öffentlichen Hand Vereinsregister-Nr. VR 751 B, Amtsgericht Charlottenburg		Institut für Arbeitsschutz der DGUV (IFA) Prüf- und Zertifizierungsstelle im DGUV Test Alte Heerstraße 111 • 53757 Sankt Augustin • Deutschland Telefon: +49 (0) 20 13001-38600 • Fax: +49 (0) 20 13005-38001

Appendix

Documentation 2

bsi.



EC Type-Examination Certificate

This is to certify that:

Suzhou Fangtian Industries Co Ltd
South of Xingfu Road, Medical Equipment of
Yandu Industrial Park, Yandu District,
Yancheng, Jiangsu
224003
China

Holds Certificate Number:

CE 555686

In respect of:

Disposable face masks to EN 149:2001+A1:2009
Various models - see continuation sheet for details

On the basis of our examination, under the requirements of Council Directive 89/686/EEC "Personal Protective Equipment" Article 10, EC Type-Examination.

For and on behalf of BSI,
a Notified Body for the above Directive
(Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: 8/12/2010

Latest Issue: 11/12/2013

„making excellence a habit.“

Page 1 of 5

This certificate remains the property of The British Standards Institution and shall be returned immediately upon request.
To check its validity telephone 444 (0)845 080 5000.

Information and contact: BSI, 389 Chiswick Park Avenue, Uxbridge, Middlesex UB8 3PH. Tel: +44 (0)845 080 5000.
BSI Assurance UK Limited, registered in England under number 7805321, at 389 Chiswick Park Avenue, London, W4 4AL, UK.
A member of the BSI Group of Companies.

Appendix

Documentation 3

第一类医疗器械生产备案凭证

备案编号：鲁济食药监械生产备 20190017 号

企业名称	山东艾克韦生物技术有限公司						
住所	山东省济南市高新区大正路 1777 号药谷产业园 15 号楼						
生产地址	山东省济南市高新区大正路 1777 号药谷产业园 15 号楼						
法定代表人	张国宁		企业负责人		张国宁		
生产范围	2002 年分类目录：Ⅰ类：6840 临床检验分析仪器（体外诊断试剂除外）， 6840 体外诊断试剂 2017 年分类目录：Ⅰ类：22 临床检验器械						
生产产品列表							
序号	产品名称	备案编号	类别	更改类型	备案日期	是否受托生产	受托截止日期
1	全自动核酸提取仪	鲁济械备 2019013 2 号	其他	无变化	2019-06-06		
2	核酸提取试剂盒（磁珠法）	鲁济械备 2019025 6 号	体外诊断试剂	无变化	2019-09-26		
3	核酸提取试剂盒（离心柱法）	鲁济械备 2019025 7 号	体外诊断试剂	无变化	2019-09-26		
4	血液核酸提取试剂盒（离心柱法）	鲁济械备 2019030 7 号	体外诊断试剂	无变化	2019-11-07		
5	血液核酸提取试剂盒（磁珠法）	鲁济械备 2019030 9 号	体外诊断试剂	无变化	2019-11-11		
6	一次性病毒采样管	鲁济械备 2020007 9 号	其他	增加	2020-02-19		

备案部门：济南市行政审批服务局

备案日期：2020 年 02 月 24 日

Appendix

Documentation 4

EC Declaration of Conformity

Manufacturer:

Shandong ACV Biotechnology Co., Ltd.

Address: Building 15 Drug Valley Industrial Park, 1777
Dazheng Lu, Licheng District, Jinan City, Shandong, China

whose single Authorized Representative:

Name: Luxus Lebenswelt GmbH

Add: Kochstr. 1, 47877, Willich, Germany

DIMDI Code: DE/0000047791

Tax Number: DE305829099

Contact Person: Lin Sun

Tel/Fax: 0049-1715605732

E-mail: Info.m@luxuslw.de

We, the manufacturer, herewith declare that the products

SARS-CoV-2 (ORF1ab / N Gene) Nucleic Acid Detection Kit (Fluorescence Qualitative RT-PCR)
Specs: 25 T/kit, 50 T/kit, 100 T/kit

meet the provisions of Directive 98/79/EC which apply to them.

The medical device has been assigned to In Vitro Diagnostic Medical Devices Directive 98/79/EC. It bears the mark



The product concerned has been designed and manufactured under a quality management system according to In Vitro Diagnostic Medical Devices Directive 98/79/EC.

following the procedure relating to the EC Declaration of Conformity set out in Annex III of Directive 98/79/EC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Shandong ACV Biotechnology Co., Ltd.

Address: Building 15 Drug Valley Industrial Park, 1777 Dazheng Lu, Licheng District, Jinan City, Shandong, China

Jinan Mar.9th, 2020

Place, date

GM

Legally binding signature, Function

Zhang Cuoning

EC Declaration of Conformity
ACV/CE-02 (Revision A/0)

Appendix

Documentation 5

检 验 报 告

报告编号：Y2020022842

委 托 方： 山东艾克韦生物技术有限公司

生产单位： 山东艾克韦生物技术有限公司

样品名称： 新型冠状病毒（2019-nCoV-ORF1ab/N 基因）核酸检

测试剂盒（荧光 PCR 法）

规格型号： 50 人份/盒

检验类别： 注册检验



国家食品药品监督管理局济南医疗器械质量监督检验中心

Appendix

Documentation 6

国家食品药品监督管理局济南医疗器械质量监督检验中心

检验报告首页

报告编号: Y2020022842

共 8 页 第 1 页

样品名称	新型冠状病毒 (2019-nCoV-ORF1ab/N 基因) 核酸检测试剂盒 (荧光 PCR 法)	样品编号	Y2020022842
来样方式	送样		
商标	/	规格型号	50 人份/盒
委托方	山东艾克韦生物技术有限公司	检验类别	注册检验
委托方地址	山东省济南市高新区大正路 1777 号 15 号楼	产品编号/批号	B7200116-0102 B7200117-0102 B7200118-0102
生产单位	山东艾克韦生物技术有限公司	抽样单编号	--
受检单位	山东艾克韦生物技术有限公司	生产日期	2020.01.16 2020.01.17 2020.01.18
抽样单位	--	样品数量	各 3 盒
抽样地点	--	抽样基数	--
抽样日期	--	检验地点	本检验中心实验室
收样日期	2020-02-28	检验日期	2020-02-29
检验项目	除稳定性外的其他项目。		
检验依据	《新型冠状病毒 (2019-nCoV-ORF1ab/N 基因) 核酸检测试剂盒 (荧光 PCR 法)》产品技术要求		
检验结论	所检项目符合《新型冠状病毒 (2019-nCoV-ORF1ab/N 基因) 核酸检测试剂盒 (荧光 PCR 法)》产品技术要求。 (检验报告专用章) 签发日期: 2020 年 3 月 4 日		
备注	1) 报告中的 "--" 表示此项不适用, 报告中 "/" 表示此项空白 2) 检测所用仪器为罗氏 LightCycler 480 II 型 荧光定量 PCR 仪		

批准:

徐晓洲

职务:

技术负责人

Appendix

Documentation 7

	
营业执照	
(副本) 1-1	
统一社会信用代码 91370100798859788J	 扫描二维码登录 “国家企业信用 信息公示系统” 了解更多登记 备案、许可、监 管信息
名称 山东艾克韦生物技术有限公司	注册资本 壹仟贰佰叁拾壹万壹仟肆佰捌拾元整
类型 其他有限责任公司	成立日期 2007年 03 月 16 日
法定代表人 张国宁	营业期限 2007年 03 月 16 日至 年 月 日
经营范围 一般项目：第一类医疗器械生产；第一类医疗器械零售；第二类医疗器械零售；医学研究和试验发展；技术服务、技术开发、技术咨询、技术交流、技术转让、技术推广；工程和技术研究和试验发展；计算机软硬件及辅助设备零售；信息技术咨询服务；生物化工产品技术研发；人体基因诊断与治疗技术开发；信息咨询服务（不含许可类信息咨询服务）；环保咨询服务；会议及展览服务；化工产品批发（不含危险化学品）；第一类医疗器械批发；第二类医疗器械批发；机械设备批发；五金产品批发；计算机软硬件及辅助设备批发；电气设备批发；办公设备批发；电子办公设备零售；五金产品零售；人体干细胞技术开发和应用（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）许可项目：第二类医疗器械生产；第三类医疗器械生产；第三类医疗器械经营；货物进出口；检验检测服务（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，具体经营项目以审批结果为准）	住 所 山东省济南市高新区大正路1777号生物医药园中小企业产业基地15号楼1F
登记机关 	
2020 年 02 月 01 日	