



证书持有人: 般诺智能(深圳)有限公司

Certificate holder: Bannuo intelligent (Shenzhen) Co., Ltd

产品型号: BBS-2、BBS-2Closed

Product model: BBS-2, BBS-2closed

CE EN166 认证

CE en166 certification

产品符合欧盟指令: PPE (EU)2016/425

Product complies with EU directives:PPE (EU)2016/425



Certificate of Conformity

Certificate number: HT20DC-0300765

Report number: HT20DR-0300765

Honton Compliance Laboratories (Shenzhen) Co., Ltd. hereby declares that testing has been completed and reports have been generated for:

Applicant: Bannuo intelligence (Shenzhen)Co.,Ltd

Address: 1801, blok a, Zhantao technology builing intersection of Minzhi Avenue and Gongye East Road, Xinniu community, Minzhi street, Longhua District, Shenzhen

Manufacturer: Bannuo intelligence (Shenzhen)Co.,Ltd

Address: No.131, Liguang Industrial Zone, Guanlan Town, Longhua District, Shenzhen

Product: Isolation eye mask/goggles

Model: BBS-2, BBS-2 Closed

Trade Mark: BAPORSSA

And, in accordance with the following applicable directives:

PPE (EU)2016/425 Personal protective equipment

That this product has been assessed against the following applicable standards:

EN 166:2001

Therefore, Honton Compliance Laboratories (Shenzhen) Co., Ltd. hereby acknowledges that the applicant may issue a DECLARATION of CONFORMITY and apply the CE marking in accordance with European Union Rules.



Attestation By:

Adam Li

Adam Li/Senior Manager

Date:

Mar. 18, 2020



160mm



公司名称：般诺智能（深圳）有限公司

品牌：巴宝莎

外箱包装规格：一箱200副，65cm*50cm*60cm
毛重9.3kg 净重：9kg

Corporate name: Bannuo intelligence (Shenzhen) Co., Ltd

Brand: BAPORSSA

Packaging specification: 200 pairs of boxes, 65cm*50cm*60cm
Gross weight:9.3KG Net weight: 9kg



内盒包装Inner box packaging



外箱包装Outer box packaging



公司名称: 般诺智能(深圳)有限公司

品 牌: 巴宝莎

内盒包装规格: 一盒10副, 27cm*19cm*8.5cm
毛重1.49kg 净重: 0.7kg

外箱 尺寸: 一箱20盒,
尺寸: 79cm*28.5cm*49cm
毛重: 17kg 净重: 14kg

Corporate name: Bannuo intelligence (Shenzhen) Co., Ltd

Brand: BAPORSSA

Inner box packing specification: one box of 10 pairs, 27cm * 19cm * 8.5cm
Gross weight 1.49kg net weight: 0.7kg

Outer box size: A box of 20 boxes.size: 79cm*28.5cm*49cm
Gross weight: 17kg net weight: 14kg

产品图

product pictures



基本存款账户信息

对公转账的账户信息
Account information of corporate transfer

账户名称: 般诺智能(深圳)有限公司

账户号码: 771872288017

开户银行: 中国银行股份有限公司深圳万科城支行

法定代表人:
(单位负责人) 张弼诚

基本存款账户编号: J5840223682901

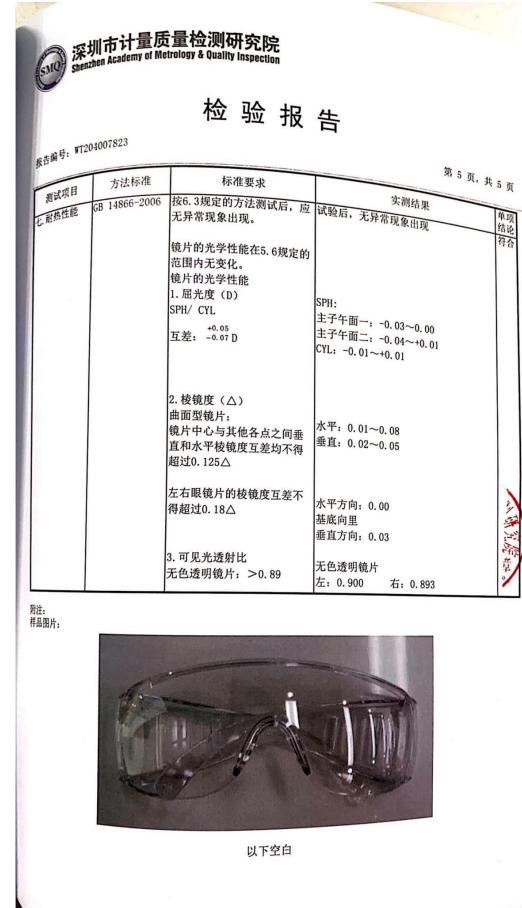
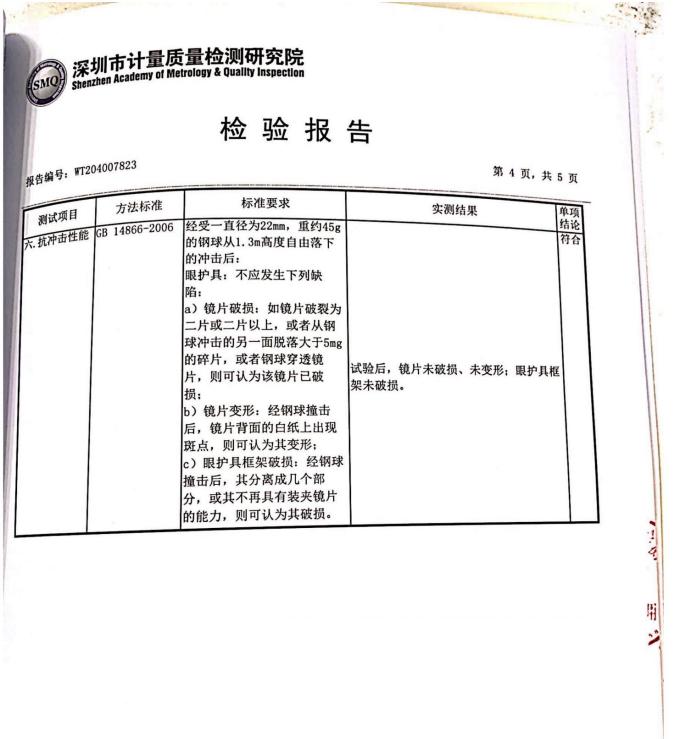
开户许可证

Account opening permit



医用护目镜检测报告

Test report of medical goggles



扫描全能王 创建



扫描全能王 创建

- **01. 公司简介**

Company Profile

- **02. 产品资质**

Product Qualification

- **03. 产品规格**

Product Specification

- **04. 产品、工厂车间图片**

Pictures of products and Workshops



CONTENTS

营业执照

Business license



第一类医疗器械生产备案

Class I medical device production record

第一类医疗器械生产备案凭证

备案号：粤深食药监械生产备 20200021 号

企业名称	般诺智能（深圳）有限公司			
住所	深圳市龙华区民治街道新牛社区民治大道与工业东路交汇处展滔科技大厦 A 座 1801			
生产场所	深圳市龙华区观澜镇黎光工业区 131 号			
法定代表人	张弼诚	企业负责人	张弼诚	
生产范围	14-14 医护人员防护用品			
生产产品 列表	产品名称	产品备案号	登载日期	备注
	医用隔离眼罩	粤深械备 20200075 号	20200220	/
	/			/
				/
				/
				/
				/
				/
				/
				/

备案部门

深圳市市场监督管理局

备案日期：2020 年 02 月 25 日

深圳市场局网站，可验证本证书。

方法 1：详见市场局网站“药械信息查询栏目”：

<https://amr.sz.gov.cn/szyj/zwgk/search.jsp>

方法 2：访问深圳市场局网站 <http://amr.sz.gov.cn>

点击首页的“政务服务”-“信息查询”-“药械信息查询”，内有一类备案等市局证书的查询界面。

以上网页，推荐 IE11 浏览器打开，并打开兼容视图设置，添加网址 sz.gov.cn。

第一类医疗器械备案凭证

般诺智能（深圳）有限公司：

根据相关法规要求，对你单位第一类医疗器械：医用
隔离眼罩 予以备案，备案号：粤深械备 20200075 号。



2020-02-20

第一类医疗器械备案信息表

备案号：粤深械备 20200075 号

备案人名称	般诺智能（深圳）有限公司
统一社会信用代码	91440300MA5FMWFQ5H
备案人注册地址	深圳市龙华区民治街道新牛社区民治大道与工业东路交汇处展滔科技大厦 A 座 1801
生产地址	深圳市龙华区观澜镇黎光工业园 131 号
产品名称	医用隔离眼罩
型号/规格	型号：BBS-2
产品描述	由高分子材料制成的防护眼罩和固定装置组成。非无菌提供，一次性使用。
预期用途	用于医疗机构中检查治疗时起防护作用，阻隔体液、血液飞溅或泼溅。
备注	
备案单位 和日期	深圳市市场监督管理局 备案日期：2020-02-20
变更情况	

深圳市场局网站，可验证本证书。

方法 1：详见市场局网站“药械信息查询栏目”：

<https://amr.sz.gov.cn/szyj/zwgk/search.jsp>

方法 2：访问深圳市场局网站 <http://amr.sz.gov.cn>

点击首页的“政务服务”-“信息查询”-“药械信息查询”，内有一类备案等市局证书的查询界面。

以上网页，推荐 IE8 及以上 IE 浏览器打开（IE10 以上请打开兼容视图模式）。

第二类医疗器械经营备案

Type II medical device business record



第二类医疗器械经营备案凭证

备案编号: 粤深食药监械经营备 20191412 号

企业名称	般诺智能(深圳)有限公司
法定代表人	张弼诚
企业负责人	马铭
经营方式	批零兼营
住 所	深圳市龙华区民治街道新牛社区民治大道与工业东路交汇处展滔科技大厦 A 座 1801
经营场所	深圳市龙华区民治街道新牛社区民治大道与工业东路交汇处展滔科技大厦 A 座 1801
库房地址	深圳市龙华区民治街道新牛社区民治大道与工业东路交汇处展滔科技大厦 A 座 1801
经营范围	2002 年分类目录 (二类) : 6801, 6802, 6803, 6804, 6805, 6806, 6807, 6808, 6809, 6810, 6812, 6813, 6815, 6816, 6820, 6821, 6822, 6823, 6824, 6825, 6826, 6827, 6828, 6830, 6831, 6832, 6833, 6834, 6841, 6845, 6846, 6854, 6855, 6856, 6857, 6858, 6863, 6864, 6865, 6866, 6870, 6877, 以上类别中包含的植入和介入类产品除外 2017 年分类目录 (二类) : 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 以上类别中包含的植入和介入类产品除外, 以上类别中包含的角膜接触镜、助听器产品除外

备案部门 (公章)



备案日期: 2020 年 02 月 18 日



医用护目镜检测报告

Test report of medical goggles



检验报告

TEST REPORT



(替代WT204006062报告)

报告编号: WT204007823

第 1 页, 共 5 页

委托单位: 般诺智能(深圳)有限公司
委托单位地址: 深圳市龙华区民治街道新牛社区民治大道与工业东路交汇处展滔科技大厦A座1801
样品名称: 医用护目镜
型号/规格/等级: BBS-2
检验类别: 送样检验
检验地点: 龙华实验基地

批准人: 郝建金

签名: 郝建金

签发日期: 2020年03月04日

深圳市计量质量检测研究院 Shenzhen Academy of Metrology & Quality Inspection <http://www.smq.com.cn>
电子邮件 (E-mail): kfzx@smq.com.cn CMA证书附录编号(CMA No.): 20171907302 & 201719001402
龙华实验基地: 深圳市龙华区民治大道民康路北114号 邮政电话: 0755-27528955 传真: 0755-27528707 邮编: 518131
Longhua Experimental Base: No.114, Minkang North Road, Minzhi Avenue, Longhua District, Shenzhen Tel:0755-27528955



扫描全能王 创建



检验报告

报告编号: WT204007823

第 2 页, 共 5 页

样品信息:

样品名称: 医用护目镜
商标: 巴宝莎
型号/规格/等级: BBS-2
样品编/批号: 20200215A
生产日期: 2020-02-15
生产单位: 般诺智能(深圳)有限公司
生产单位地址: 深圳市龙华区观澜街道黎光社区黎光新工业区131号(厂房五)整套
样品数量: 5 抽样基数: _____
抽样地点: _____
抽样人员: _____
检前样品描述: 正常。

客户信息:

委托单位: 般诺智能(深圳)有限公司
委托单位地址: 深圳市龙华区民治街道新牛社区民治大道与工业东路交汇处展滔科技大厦A座1801
委托单位电话: 13641466664
邮政编码: _____
受检单位: _____

检验信息:

委托日期: 2020年02月26日 委托单号: 6953666
检验类别: 送样检验 获样方式: 送样
检验日期: 2020年02月26日至2020年03月04日
检验环境条件: (18~25)°C (50~70)%RH
判定依据: GB 14866-2006
检测依据: GB 14866-2006

检验结论:

检验结果见附页。

主检: 杨珂 托丽

审核: 陈开江 陈开江



扫描全能王 创建

测试项目	方法标准	标准要求	实测结果	单项结论
一、结构	GB 14866-2006	1. 表面光滑、无毛刺、无锐角或可能引起眼面部不舒适感的其他缺陷; 2. 应具有良好的透气性; 3. 可调节零件或结构部件应易于调节和替换。	符合	符合
二、头箍	GB 14866-2006	在与佩戴者接触的任一部分头箍至少应保持10mm宽, 头箍应能调节, 选用的材料应质地柔软, 经久耐用。	不适用	
三、镜片规格	GB 14866-2006	单镜片: 长×宽尺寸不小于105mm×50mm;	142.47mm×53.93mm	符合
四、镜片的外观质量	GB 14866-2006	镜片表面应光滑、无划痕、波纹、气泡、杂质或其他可能有损视力的明显缺陷。	符合	符合
五、光学性能	GB 14866-2006	SPH/ CYL	SPH: 主子午面一: -0.01~-+0.03 主子午面二: -0.02~-+0.05 CYL: -0.02~-+0.02	符合
1. 屈光度 (D)	GB 14866-2006	互差: +0.05 -0.07 D		
2. 棱镜度 (△)	GB 14866-2006	曲面型镜片: 镜片中心与其他各点之间垂直和水平棱镜度互差均不得超过0.125△ 左右眼镜片的棱镜度互差不得超过0.18△	水平方向: 0.05 垂直方向: 0.05 基底向外: 0.05 垂直方向: 0.00	符合
3. 可见光透射比	GB 14866-2006	无色透明镜片: >0.89	无色透明镜片 左: 0.897 右: 0.893	符合



扫描全能王 创建

CE EN166 认证

CE en166 certification



Page 1 of 11

Report No. : HT20DR-0300945

Test Report	
EN 166 Personal eye-protection — Specifications	
Report reference No.....	: HT20DR-0300945
Tested by (name+ signature).....	Eden Yu
Approved by (name+ signature).....	Michnel Lin
Date of issue.....	: Mar. 19, 2020
Testing Laboratory Name.....	: Honton Compliance Laboratories (Shenzhen) Co., Ltd.
Address.....	: 5/F, Building C, No. 73, Huahui Road, Dalang Street, Longhua District, Shenzhen 518109, China
Testing location	: Same as above
Applicant's Name.....	: Bannuo intelligence (Shenzhen)Co.,Ltd
Address.....	: 1801, blok a, Zhanqiao technology building intersection of Minzhi Avenue and Gongye East Road, Xinniu community, Minzhi street, Longhua District, Shenzhen
Standard.....	: EN 166:2001
Test procedure.....	: Type test
Procedure deviation.....	: N/A.
Non-standard test method.....	: N/A.
Test item description.....	: Isolation eye mask/goggles
Manufacturer.....	: Bannuo intelligence (Shenzhen)Co.,Ltd
Address.....	: No.131, Liguang Industrial Zone, Guanlan Town, Longhua District, Shenzhen
Trademark.....	: BAPORSSA
Model / Type reference	: BBS-2, BBS-2 Closed



Page 2 of 11

Report No. : HT20DR-0300945

Summary of testing:

Tests performed (name of test and test clause):

- EN 166:2001

The submitted samples were found to comply with the requirements of above specification

Test item particulars

Operation condition: Continuous

Possible test case verdicts:

- test case does not apply to the test object.....: N (N/A)

- test object does meet the requirement.....: P (Pass)

- test object does not meet the requirement.....: F (Fail)

Testing:

Date of receipt of test item: Mar. 13, 2020

Date(s) of performance of test: Mar. 13, 2020 to Mar. 19, 2020

Attachment No.1: Photo-documentation

Copy of label:



Note: 1. CE mark at least 5mm.
2. All models are similar except for the model name and rating.



Page 3 of 11

Report No. : HT20DR-0300945

General remarks:

"(see remark #)" refers to a remark appended to the report.

"(see appended table)" refers to a table appended to the report.

Throughout this report a comma is used as the decimal separator.

The test results presented in this report relate only to the object tested.

This report shall not be reproduced, except in full, without the written approval of the issuing testing laboratory.

Unless otherwise specified, test are made under normal conditions at an ambient temperature within the range of 15°C to 35°C , RH45% to 75% and an air pressure of 860mbar of 1060mbar

General product information:

Isolation eye mask/goggles, model BBS-2, BBS-2 Closed. All tests were carried out on model BBS-2.

CE EN166 认证

CE en166 certification



Honton Compliance Lab

Page 4 of 11

Report No. : HT20DR-0300945

Clause	Requirement – Test	Result - Remark	Verdict
7	Basic, particular and optional requirements	P	
7.1	Basic requirements	P	
7.1.1	Field of vision	P	
	The size of the field of vision is defined in conjunction with the appropriate head-form described in clause 17 of EN 168:2001.	P	
7.1.2	Optical requirements	P	
7.1.2.1	Spherical, astigmatic and prismatic refractive powers	P	
	The refractive powers of oculars shall be measured by the reference methods specified in clause 3 of EN 167:2001	P	
7.1.2.1.1	Unmounted oculars covering one eye	N	
	The refractive power characteristics of unmounted oculars covering one eye shall be measured by the method specified in 3.1 of EN 167:2001 (non-corrective oculars), and by the methods specified in EN ISO 8980-3 (corrective oculars).	N	
7.1.2.1.2	Mounted oculars and unmounted oculars covering both eyes	P	
	The refractive power characteristics of mounted oculars or unmounted oculars covering both eyes shall be measured by the method specified in 3.2 of EN 167:2001 at the visual centre of the ocular.	P	
7.1.2.1.3	Cover plates	P	
	The refractive powers of cover plates shall comply with the tolerances for optical class 1 given in Tables 2 and 3.	P	
7.1.2.2	Transmittance	P	
7.1.2.2.1	Oculars without filtering action	P	
	Oculars intended to protect the eyes against mechanical or chemical hazards only, and cover plates, shall have a luminous transmittance greater than 74.4 % when measured as given in clause 6 of EN 167:2001 (based on CIE source A (2856 K)).	P	
7.1.2.2.2	Oculars with filtering action (filters) and housings for oculars with filtering action.	N	
	The transmittance of oculars with filtering action shall meet the requirements given in the specific standards relating to the various types of ocular (see 7.2.1).	N	
7.1.2.2.3	Variations in transmittance (Oculars without filtering action are exempt from this requirement)	N	
7.1.2.2.3.1	Oculars without corrective effect	N	



Honton Compliance Lab

Page 5 of 11 Report No. : HT20DR-0300945

Clause	Requirement – Test	Result - Remark	Verdict
	Variations in luminous transmittance shall be measured in accordance with clause 7 of EN 167:2001.	N	
7.1.2.2.3.2	Oculars with corrective effect (prescription oculars)	N	
	The requirements of 7.1.2.2.3.1 shall also apply to prescription oculars, with the provision that variations in luminous transmittance which are due to thickness variations inherent in the design of the ocular are not taken into account, providing the luminous transmittance at no point deviates by more than a factor of 2.68 (one shade number) from its value at the visual centre.	N	
7.1.2.3	Diffusion of light	P	
	The diffusion of light shall be measured in accordance with one of the reference methods specified in clause 4 of EN 167:2001.	P	
7.1.3	Quality of material and surface	P	
	Except for a marginal area 5 mm wide, oculars shall be free from any significant defects likely to impair vision in use, such as bubbles, scratches, inclusions, dull spots, pitting, mould marks, scouring, grains, pocking, scaling and undulation.	P	
7.1.4	Robustness	P	
7.1.4.1	Minimum robustness	N	
	This requirement relates only to cover plates and oculars with filtering effect and need not be assessed if these items are intended to meet the requirements for increased robustness or resistance to high speed particles, in which case the requirements of 7.1.4.2 or 7.2.2 shall be met.	N	
7.1.4.2	Increased robustness	P	
7.1.4.2.1	Unmounted oculars	N	
	The oculars shall withstand the impact of a 22 mm nominal diameter steel ball, of 43 g minimum mass, striking the ocular at a speed of approximately 5,1 m/s, when tested in accordance with 3.1 of EN 168:2001.	N	
7.1.4.2.2	Complete eye-protectors and frames	P	
	The complete eye-protector or frame shall withstand the lateral and frontal impacts of a steel ball striking at a specified speed.	P	
7.1.5	Resistance to ageing	P	
7.1.5.1	Stability at an elevated temperature	P	



Honton Compliance Lab

Page 6 of 11 Report No. : HT20DR-0300945

Clause	Requirement – Test	Result - Remark	Verdict
	Assembled eye-protectors shall show no apparent deformation when tested by the method specified in clause 5 of EN 168:2001.	P	
7.5.1.2	Resistance to ultraviolet radiation (oculars only)	P	
	Oculars shall be subjected to the test for resistance to ultraviolet radiation in accordance with the method specified in clause 6 of EN 168:2001.	P	
7.1.6	Resistance to corrosion	N	
	After having undergone the test for resistance to corrosion specified in clause 8 of EN 168:2001, all metal parts of the eye-protector shall display smooth surfaces, free from corrosion, when they are examined by a trained observer.	N	
7.1.7	Resistance to ignition	P	
	Eye-protectors shall be tested in accordance with the method specified in clause 7 of EN 168:2001 and shall be considered to be satisfactory if no part of the eye-protector ignites or continues to glow after removal of the steel rod.	P	
7.2	Particular requirements	P	
7.2.1	Protection against optical radiation	N	
7.2.2	Protection against high-speed particles	P	
	Eye-protectors intended to provide protection against high-speed particles shall withstand the impact of a 6 mm nominal diameter steel ball of 0.66 g minimum mass, striking the oculars and the lateral protection at one of the speeds given in Table 7.	P	
7.2.3	Protection against molten metals and hot solids	N	
7.2.4	Protection against droplets and splashes of liquids	P	
	Eye-protectors for use against droplets (goggles) and splashes of liquids (face-shields) shall be tested in accordance with the methods specified in clause 12 of EN 168:2001.	P	
7.2.5	Protection against large dust particles	P	
	Eye-protectors for use against large dust particles shall be tested in accordance with the method specified in clause 13 of EN 168:2001.	P	
7.2.6	Protection against gases and fine dust particles	P	
	Eye-protectors for use against gases and fine dust particles shall be tested in accordance with the method specified in clause 14 of EN 168:2001.	P	
7.2.7	Protection against short circuit electric arc	N	

CE EN166 认证

CE en166 certification



Honton Compliance Lab

Page 7 of 11

Report No. : HT20DR-0300945

Clause	Requirement – Test	Result - Remark	Verdict
	Eye-protectors for protection against short circuit electric arc shall be face-shields only.		N
7.2.8	Lateral Protection		N
	Eye-protectors claimed to provide lateral protection shall pass the lateral region coverage assessment detailed in clause 19 of EN 168:2001.		N
7.3	Optional requirements		P
	Optional requirements are specified for additional characteristics of eye-protectors which may be found to be beneficial to the user for operational reasons.		P
7.3.1	Resistance to surface damage by fine particles		N
	If oculars are described as resistant to surface damage by fine particles they shall have a reduced luminance factor of not more than $5 \frac{\text{cd}}{\text{m}^2 \cdot \text{lx}}$ following the test specified in clause 15 of EN 168:2001.		N
7.3.2	Resistance to fogging of oculars		N
	If oculars are described as resistant to fogging they shall remain free from fogging for a minimum of 8 s when tested in accordance with clause 16 of EN 168:2001.		N
7.3.3	Oculars with enhanced reflectance in the infrared		N
	Oculars which are claimed to have enhanced reflectance in the infrared shall have a mean spectral reflectance greater than 60 % within the wavelength range 780 nm to 2 000 nm when measured in accordance with clause 8 of EN 167:2001.		N
7.3.4	Protection against high speed particles at extremes of temperature		N
	Eye-protectors intended to provide protection against high-speed particles at extremes of temperature shall withstand the impact of a 6 mm nominal diameter steel ball of 0.86 g minimum mass, striking the oculars and the lateral protection at one of the speeds given in Table 7.		N
8	Allocation of requirements, test schedules and application		P
8.1	Requirements and test methods		P
	The requirements and test methods for oculars and complete eye-protectors are specified in various European Standards (see clause 2).		P
8.2	Test schedules for type examination		P
	The necessary number of samples for type examination and the required order of the individual tests to be carried out are shown in Table 10		P



Honton Compliance Lab

Page 8 of 11

Report No. : HT20DR-0300945

Clause	Requirement – Test	Result - Remark	Verdict
	(mounted and unmounted oculars) and Table 11 (frames and complete eye-protectors).		
8.3	Application of eye-protector types		P
	The application of eye-protector types to the various fields of use is shown in Table 12.		P
9	Marking		P
9.1	General		P
	All markings shall be clear and permanent.		P
9.2	Ocular marking		P
9.2.1	Scale number		P
9.2.2	Identification of the manufacturer		P
9.2.3	Optical class		P
9.2.4	Mechanical strength		P
9.2.5	Resistance to short circuit electric arc		N
9.2.6	Non-adherence of molten metal and resistance to penetration of hot solids		P
9.2.7	Resistance to surface damage by fine particles		N
9.2.8	Resistance to fogging of oculars		N
9.2.9	Original/replacement oculars		P
9.2.10	Resistance to high speed particles at extremes of temperature		N
9.2.11	Marking of laminated oculars		N
9.2.12	Examples of ocular marking		N
9.3	Frame marking		P
9.3.1	Identification of the manufacturer		P
9.3.2	The number of this standard		P
9.3.3	Field of use		P
9.3.4	Increased robustness and resistance to high speed particles		N
9.3.5	Resistance to high speed particles at extremes of temperature		N
9.3.6	Frames designed to fit a small head		N
9.3.7	Highest ocular scale number		N
9.3.8	Examples of frame marking		P
9.4	Marking of eye-protectors where the frame and ocular form a single unit		N
10	Information supplied by the manufacturer		P
	The manufacturer shall provide with each eye-protector, replacement ocular and replacement frame at least the following information:		P
	a) name and address of the manufacturer;		P



Honton Compliance Lab

Page 9 of 11

Report No. : HT20DR-0300945

Clause	Requirement – Test	Result - Remark	Verdict
b)	the number of this standard;		P
c)	the eye-protector model identification;		P
d)	instructions for storage, use and maintenance;		P
e)	specific instructions for cleaning and disinfection;		P
f)	details of the field of use, protection capabilities and performance characteristics;		P
g)	details of suitable accessories and spare parts. Instructions for fitting shall be included with the original eye-protector and/or with the spare part or accessory;		P
h)	the obsolescence deadline or period of obsolescence, if applicable, for the complete eye-protector and/or component parts;		P
i)	the type of packaging suitable for transport, if applicable;		P
j)	the significance of the marking on the frame and the ocular;		P
k)	a warning that optical class 3 oculars are not intended for long term use, if applicable;		P
l)	a warning concerning the compatibility of marking (see notes (4), (5) and (6) to Table 12);		P
m)	a warning that materials which may come into contact with the wearer's skin could cause allergic reactions to susceptible individuals;		P
n)	a warning that scratched or damaged oculars should be replaced;		P
o)	a warning that eye-protectors against high speed particles worn over standard ophthalmic spectacles may transmit impacts, thus creating a hazard to the wearer;		N
p)	a note to instruct that if protection against high speed particles at extremes of temperature is required then the selected eye-protector should be marked with the letter T immediately after the impact letter, i.e. FT, BT or AT. If the impact letter is not followed by the letter T then the eye protector shall only be used against high speed particles at room temperature.		N

CE EN166 认证

CE en166 certification



Page 10 of 11

Report No. : HT20DR-0300945

Photo-documentation

Photo 1 General Appearance of the EUT



Photo 2 General Appearance of the EUT



Page 11 of 11

Report No. : HT20DR-0300945

Photo 3 General Appearance of the EUT



Photo 4 General Appearance of the EUT



End of report

产品说明书

产品说明书

【产品名称】医用隔离眼罩

说明书版本: A/0

说明书编制日期: 2020年2月25日

【产品型号规格】

BBS-2

【产品描述(主要机构组成)】通常由高分子材料制成的防护罩和固定装置组成。非无菌提供,一次性使用。

【产品适用范围】用于医疗机构中检查治疗时起防护作用,阻隔体液、血液飞溅或泼溅。

【禁忌症】无。

【产品性能】

材料及表面质量

镜片表面应光滑、无划痕、波纹、气泡、杂质或者其他可能有损视力的明显缺陷。

【安装与使用说明】

拆开包装,取出医用隔离眼罩,戴在眼镜部位,调节镜架固定。

【注意事项】

1、本产品为一次性使用。

2、使用后以医疗废弃物处理。

【警示以及提示的内容】无

【维护和保养】

1. 在使用过程中,产品外观破裂禁止使用。

2. 产品遇有故障,请与我公司或当地经销商联系。

【贮存】相对湿度≤80%,无腐蚀性气体、阴凉、干燥、通风良好的环境内。避免超体积堆放,防止重压。

【配件清单】医用隔离眼罩×1套、说明书×1份、合格证×1份/箱。

【生产日期】见标签

【使用期限】3年

医疗器械生产备案凭证编号:粤深食药监械生产备20200021号

医疗器械产品备案凭证编号:粤深械备20200075号

医疗器械产品技术要求编号:粤深械备20200075号

生产企业(备案人):般诺智能(深圳)有限公司

注册地址(备案人住所):龙华区民治街道展滔科技大厦A座1801

生产企业生产地址:龙华区观澜镇黎光工业区131号

电 话: [REDACTED]

邮 编: 518000

售后服务: [REDACTED]

Product Manual

[Production Product name] Medical compartment from goggles specification Version: A / 0

Manual preparation date: 2020 Nian 2 Yue 25 Ri

[Product type grid]

BBS-2 / BBS-2 fully enclosed

[Product description (main mechanism composition)] It usually consists of a protective cover and a fixing device made of polymer materials. Provided non-sterile,-for single use.

[Yield products suitable range] from the time for medical examination and treatment of the protective effect, the barrier fluid, blood splatter or splash.

[Contraindications] None.

[Product performance] The material and surface quality of the lens surface should be smooth, without scratches, ripples, bubbles, impurities or other obvious defects that may damage vision.

[Installation and use instructions]

Remove the packaging, take the medical isolating eye mask, wear it on the glasses and adjust the frame to fix it.

[Notes]

1. This product is for single use.

2 . After treatment with the use of medical waste.

[Contents of warnings and reminders] None

[Maintenance and maintenance]

1. During use, the appearance of the product is cracked and prohibited to use.

2. If the product is faulty, please contact our company or local distributor.

[Storage] Relative humidity ≤ 80%, non-corrosive gas, cool, dry, well-ventilated environment. Avoid over-stacking and prevent heavy pressure.

[Parts List] medical isolation goggles X1 sets, manual X1 copies , certificate X1 copies / box.

[Production date] see label

[Deadline] 3 years

Medical Device Production Filing Certificate No.: Guangdong-Shenzhen Food and Drug Supervision Equipment Production No. 20200021
Medical Device Product Recording Voucher Number: Yueshen Machinery No. 20200075

Medical device products to technology requirements : Guangdong deep mechanical equipment 20,200,075 No.

Production enterprise (filer): Banuo Intelligent (Shenzhen) Co., Ltd.

Registered address (registered office): 1801, Block A, Zhantao Technology Building, Minzhi Street, Longhua District

Production enterprises of Health yield Address: Guanlan Town, Le Quang work area Longhua District 131 No.

Phone: [REDACTED]

Postcode: 518000

After-sales service: [REDACTED]

Product manual



产 品 规 格

Product specification

Part 03

合格证标签

Certificate label

医用隔离眼罩

检验合格 CE

- 一次性使用，用后销毁
- 产品有效期：三年
- 包装破坏，严禁使用

产品描述：通常由高分子材料制成的防护罩和固定装置组成。非无菌提供，一次性使用。

适用范围：用于医疗机构中检查治疗时起防护作用，阻隔体液、血液飞溅或泼洒。

备案人：般诺智能（深圳）有限公司

生产地址：龙华区观澜镇黎光工业区131号

品牌：巴宝莎/BAPORSSA

LOT 生产批号：20200321

生产日期：20200321

規格型号：BBS-2/BBS-2closed

生产备案凭证号：粤深食药监械生产备 20200021 号

产品备案凭证号：粤深械备 20200075 号

产品技术要求编号：粤深械备 20200075 号



阅读说明 一次性使用



其他内容详见说明书

中文包装贴标

BAPORSSA®

Isolate Blindfold

Product: Isolate Blindfold

- Standard: EN166:2001 CE
- Disinfection can be reused
- Packaging is damaged forbid use
- Specifications: BBS-2/BBS-2 Closed

Date in produced: 03/22/2020

英文包装贴标
English packaging label

Scope of application: used in medical institutions for protection during inspection and treatment, blocking body fluids, blood splashing or splashing.

Recorder: Banuo Intelligent (Shenzhen) Co., Ltd.



Read the instructions



disposable

Made In China

Part 04

产品工厂车间图

Workshop drawing of Product Factory

产品图

product pictures



防飞溅挡沙尘

聚碳酸酯镜片，有效防护液体飞溅，喷漆涂鸦
农药喷洒，骑行挡风阻尘



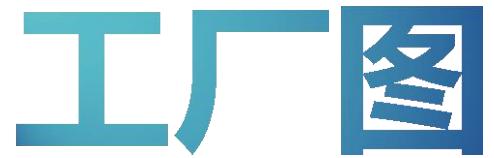
安全防护

防飞沫 防冲击物 防粉尘 防紫外线



使用展示





Factory pictures



车间图

Shop floor pictures



THANKS

謝 謝 觀 看

The Future Needs Us To Create, Only In This Way Can We Achieve Our Psychological Aspirations And Goals,
There Are Always Difficulties And Obstacles On The Way Forward, We Still Need To Face And Overcome All
Difficulties.