



Notified Body No. 1023  
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.**  
trida Tomase Bati 299, Louky, 763 02 Zlin, Czech Republic  
www.itczlin.cz

# EU Type-Examination Certificate

## No. 20 0393 T/NB

issued in the compliance with the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC, for personal protective equipment of category II:

### **Protective Face Shield** **Type: Face shield ST001**

Manufacturer:

**Shenzhen Stardeal Industrial Co. Ltd.**  
**4/F, No. 18, Rongshuxia Industrial Zone, Tongxin Community, Baolong Street, Longgang District**  
**Shenzhen, 518116 Guangdong, China**  
*Tax Registration No: 91440300760464035J*

This Certificate confirms that above referenced personal protective equipment (PPE) fulfils the essential health and safety requirements as they are stated in the Regulation (EU) 2016/425 of the European Parliament and of the Council, specified in detail in the non-harmonized technical standard:

**EN 166:2001** [*ocular without filtering and corrective effect, optical class 1, basic use + increased robustness - S*]

The PPE is produced in compliance with the manufacturer's technical file and it can be used in complete safety for its intended purpose. The detailed product descriptions, the results of technical file examination as well as the test results including their evaluation are presented in the ITC's Evaluation Report No. 723301977/2020 that is an integral part of this Certificate.

*Condition of this certificate use and related information:*

- 1. It applies only to the above referenced type of category II PPE submitted to test.*
- 2. It does not imply that the Notified Body has performed any surveillance or control of PPE manufacture.*
- 3. The manufacturer is obligated to assure that all PPEs of the respective type conform to the type approved by this Certificate.*
- 4. The applicant shall inform the Notified Body of all technology changes in manufacture of the approved type and as consequence of the technical advances he shall regularly keep himself informed of any standard changes as well as modifications of testing methods conducted by the Notified Body, which shall approve these changes in necessary cases by the amendment of this Certificate, which shall approve these changes in necessary cases by the amendment of this Certificate.*
- 5. After fulfilling the relevant EU legislation requirements, the manufacturer shall affix to each PPE, of the above referenced type, the CE-marking according to principles laid down in Regulation (EC) no. 765/2008.*



Issued in Zlin, on **31<sup>st</sup> August 2020**  
Valid until: **30<sup>th</sup> August 2025**

**Mgr. Jiří Heš**  
Representative of the Notified Body No. 1023



**INSTITUTE FOR TESTING AND CERTIFICATION, INC.**

třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

**EVALUATION REPORT**

**Ref. No.: 723301977/2020**

**Customer:** Shenzhen Stardeal Industrial Co. Ltd.  
4/F, No. 18, Rongshuxia Industrial Zone,  
Tongxin Community, Baolong Street,  
Longgang District  
Shenzhen, 518116 Guangdong, China

**Product:** Protective Face Shield  
Type: Face shield ST001

**Author:** Dipl. Ing. Elena Tomanová

**Issued on:** 2020-08-31



**Mgr. Jiří Heš**  
Representative of Notified Body No. 1023



## Introduction

This Evaluation Report was issued on the basis of Application No. 723301977 for the assessment of conformity of personal protective equipment (PPE) with the basic requirements of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.

This assessment should prove the fulfilment of EU legislation requirements for the purpose of the access of the assessed products to the EU market.

### 1. Identification of assessed personal protective equipment

A detailed description of the design and structure, including the drawing documentation and specifications of material used, is given in the file of technical documentation of the product Protective Face Shield, type: Face shield ST001.

The submitted documentation covers the following model:

Sample No. 723301977/01

Protective Face Shield, type: Face shield ST001

#### Material specification:

Sample number	Name of the product	Materials
723301977/01	Protective Face Shield Type: Face shield ST001	<u>Plastic sheet material:</u> double-sided anti-fog transparent PET Elastic band

#### Protection function:

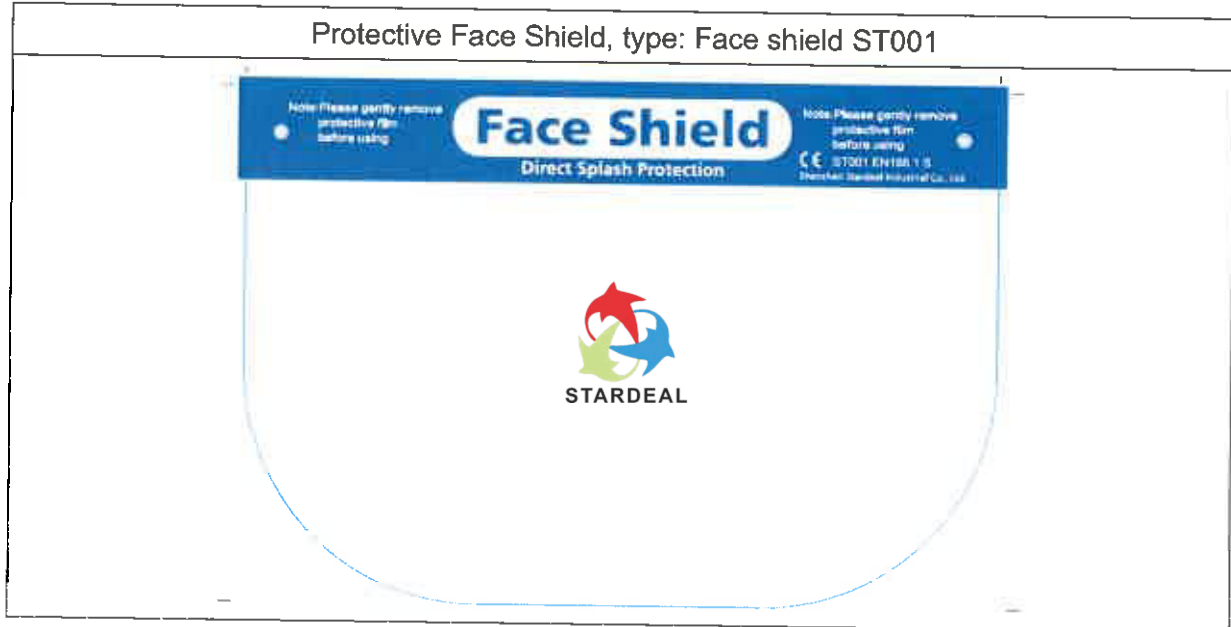
Protective Face Shield: without filtering effect (**optical class 1**).

Eye and face protection for basic use + increased robustness (**S**).

#### Classification:

Protective Face Shield, type: Face shield ST001 is classified as PPE **Category II** by the manufacturer.

Design:



## 2. Technical documentation

Technical documentation was submitted in the English language to assess the conformity of the Protective Face Shield, type: Face shield ST001 on 2020-08-31. The file of technical documentation contains the items in according to Annex III of the Regulation (EU) 2016/425 of the European Parliament and of the Council.

## 3. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC

### 3.1 *Basic requirements for the product and its specification in technical specifications*

Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC setting out technical requirements for personal protective equipment.

Tables No. 1 through 3 state the analysis of applicability of basic requirements according to Annex II of Regulation (EU) 2016/425 in the right column, supplemented in case of applicable requirements by articles of harmonised standards stated in their harmonisation annex ZA or other technical specifications used for proving the conformity with respective partial requirement.

"A" letter in the third column of the tables means that these requirements has been used for the given PPE, the "N/A" abbreviation (not applicable) means the requirement does not apply to the given PPE because it is irrelevant for the given intended use and/or the material used.

Column 4 of Tables No. 1 – 3 states the articles of harmonised standards which are linked, by means of cross links in the harmonisation annex ZA, to the respective basic requirement of Regulation (EU) 2016/425. Meeting these articles of the harmonised standard proves the conformity of the product with the given basic requirement stated in the right column.



The fifth column of Tables No. 1 – 3 states the articles of non-harmonised technical specifications by which the manufacturer proves the conformity with the respective basic requirement which is not included in harmonisation. These can be articles of non-harmonised national or international standards as well as articles of harmonised standards which are not connected with the given requirement by a link in the harmonisation annex ZA. In extraordinary cases, the respective basic requirement can be set quite specifically by the Regulation so the conformity can be assessed directly with this article of the Regulation without any necessity to specify the required by means of a harmonised standard or other technical specification.

In case of applicable requirements, the last column of Tables No. 1– 3 states the assessment of the given requirement, whether PPE passes or does not pass. "P" letter means PPE passes the given requirement, "N/P" means it does not pass it.

*Table 1: Overview of basic requirements and technical specifications used in the PPE design. General requirements applicable to all PPE*

Requirement number in Annex II	Requirement description	Application A – N/A	Article of the harmonised standard specifying the requirement (according to Annex ZA)	Other technical specification or the manner of proving the compliance with the requirement	Assessment P – N/P
1.1	Design principles	A	EN 166 art. 6.1, 6.2, 6.3		P
1.1.1	Ergonomics	A	EN 166 art. 6.3, 7.1.1		P
1.1.2	Levels and classes of protection	A	EN 166 art. 7.1		P
1.1.2.1	Optimum level of protection	A	EN 166 art. 7.1		P
1.1.2.2	Classes of protection appropriate to different levels of risks	A	EN 166 art. 7.1		P
1.2	Innocuousness of PPE	A		See requirement 1.2.1, 1.2.1.1, 1.2.1.2 and 1.2.1.3 below	P
1.2.1	Absence of risks and other inherent nuisance factors	A		See requirement 1.2.1.1, 1.2.1.2 and 1.2.1.3 below	P
1.2.1.1	Suitable constituent materials	A	EN 166 art. 6.2		P
1.2.1.2	Satisfactory surface condition of all PPE parts in contact with the user	A	EN 166 art. 6.1		P
1.2.1.3	Maximum permissible user impediment	A	EN 166 art. 6.3, 7.1.1		P
1.3	Comfort and effectiveness	A	EN 166 art. 6.3, 7.1.1		P
1.3.1	Adaptation of PPE to user morphology	A	EN 166 art. 6.3, 7.1.1		P
1.3.2	Lightness and design strength	A	EN 166 art. 7.1.4		P
1.3.3	Compatibility of different classes or types of PPE designed for simultaneous use	N/A			





Requirement number in Annex II	Requirement description	Application A – N/A	Article of the harmonised standard specifying the requirement (according to Annex ZA)	Other technical specification or the manner of proving the compliance with the requirement	Assessment P – N/P
1.3.4	Protective clothing containing removable protectors	N/A			
1.4	Manufacturer's instructions and information	A	EN 166 art. 10		P

*Table 2: Overview of basic requirements and technical specifications used in the PPE designing. Additional requirements common to several classes or types of PPE*

Requirement number in Annex II	Requirement description	Application A – N/A	Article of the harmonised standard specifying the requirement (according to Annex ZA)	Other technical specification or the manner of proving the compliance with the requirement	Assessment P – N/P
2.1	PPE incorporating adjustment systems	A	EN 166 art. 6.3		P
2.2	PPE enclosing the parts of the body to be protected	N/A			
2.3	PPE for the face, eyes and respiratory system	A	EN 166 all articles (except of art. 7.2)		P
2.4	PPE subject to ageing	A	EN 166 art. 7.1.5		P
2.5	PPE which may be caught up during use	N/A			
2.6	PPE for use in potentially explosive atmospheres	N/A			
2.7	PPE intended for rapid intervention or to be put on or removed rapidly	N/A			
2.8	PPE for intervention in very dangerous situations	N/A			
2.9	PPE incorporating components which can be adjusted or removed by the user	A	EN 166 art. 6.3		P
2.10	PPE for connection to complementary equipment external to the PPE	N/A			
2.11	PPE incorporating a fluid circulation system	N/A			
2.12	PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety	A	EN 166 art. 9		P
2.13	PPE capable of signalling the user's presence visually	N/A			



Requirement number in Annex II	Requirement description	Application A – N/A	Article of the harmonised standard specifying the requirement (according to Annex ZA)	Other technical specification or the manner of proving the compliance with the requirement	Assessment P – N/P
2.14	'Multi-risk' PPE	A	EN 166 all articles (except of art. 7.2)		P

**Table 3:** Overview of basic requirements and technical specifications used in the PPE designing. Additional requirements specific to particular risks

Requirement number in Annex II	Requirement description	Application A – N/A	Article of the harmonised standard specifying the requirement (according to Annex ZA)	Other technical specification or the manner of proving the compliance with the requirement	Assessment P – N/P
3.1	Protection against mechanical impact	A	EN 166 art. 7.1.4		P
3.1.1	Impact caused by falling or ejected objects and collision of parts of the body with an obstacle	A	EN 166 art. 7.1.4		P
3.1.2	Falls	N/A			
3.1.2.1	Prevention of falls due to slipping	N/A			
3.1.2.2	Prevention of falls from a height	N/A			
3.1.3	Mechanical vibration	N/A			
3.2	Protection against static compression of part of the body	N/A			
3.3	Protection against mechanical injuries	N/A			
3.4	Protection in liquids	N/A			
3.4.1	Prevention of drowning	N/A			
3.4.2	Buoyancy aids	N/A			
3.5	Protection against the harmful effects of noise	N/A			
3.6	Protection against heat and/or fire	N/A			
3.6.1	PPE constituent materials and other components	N/A			
3.6.2	Complete PPE ready for use	N/A			
3.7	Protection against cold	N/A			
3.7.1	PPE constituent materials and other components	N/A			
3.7.2	Complete PPE ready for use	N/A			
3.8	Protection against electric shock	N/A			
3.8.1	Insulating equipment	N/A			
3.8.2	Conductive equipment	N/A			
3.9	Radiation protection	A		EN 166 art. 7.1.2.2	P
3.9.1	Non-ionising radiation	A		EN 166 art. 7.1.2.2	P
3.9.2	Ionising radiation	N/A			



Requirement number in Annex II	Requirement description	Application A – N/A	Article of the harmonised standard specifying the requirement (according to Annex ZA)	Other technical specification or the manner of proving the compliance with the requirement	Assessment P – N/P
3.9.2.1	Protection against external radioactive contamination	N/A			
3.9.2.2	Protection against external irradiation	N/A			
3.10	Protection against substances and mixtures which are hazardous to health and against harmful biological agents	N/A			
3.10.1	Respiratory protection	N/A			
3.10.2	Protection against cutaneous and ocular contact	N/A			
3.11	Diving equipment	N/A			

When designing the product, the manufacturer applied the following standard harmonised to Regulation (EU) 2016/425:

**EN 166:2001** Personal eye protection – Specifications

### 3.2 Indicators specifying basic requirements and test methods

Indicators specifying applicable basic requirements (marked with "A" in the third column of Tables No. 1 through 3):

#### • Design and manufacturing requirements

- General construction
- Materials
- Headbands

#### • Basic requirements

- Field of vision
- Optical requirements
  - Spherical refractive power
  - Astigmatic refractive power
  - Prismatic refractive power
  - Transmittance
  - Diffusion of light

#### • Quality of material and surface

- Increased robustness
- Resistance to ageing
  - Stability at an elevated temperature
  - Resistance to ultraviolet radiations
- Resistance to ignition

#### • Marking

#### • Information supplied by the manufacturer





### 3.3 Test methods

Table No. 4: Overview of test methods used for evaluating the materials and product

Properties	Test method
<b>Design and manufacturing requirements</b>	
- General construction	visual assessment
- Materials	visual assessment
- Headbands	measured with metal ruler
<b>Basic requirements</b>	
- Field of vision	art. 18 EN 168
<b>Optical requirements</b>	
- Spherical refractive power	art. 3 EN 167
- Astigmatic refractive power	
- Prismatic refractive power	
- Transmittance	art. 6 EN 167
- Diffusion of light	art. 4 EN 167
<b>Quality of material and surface</b>	art. 5 EN 167
<b>Increased robustness</b>	art. 3.1 EN 168
<b>Resistance to ageing</b>	
- Stability at an elevated temperature	art. 5 EN 168
- Resistance to ultraviolet radiations	art. 6 EN 168
<b>Resistance to ignition</b>	art. 7 EN 168
<b>Marking</b>	visual assessment
<b>Information supplied by the manufacturer</b>	visual assessment

### 3.4 Place and scope of sampling

Samples of the assessed product were delivered by the Customer on 2020-06-15 in compliance with the instruction of the designated worker of the NB at the quantity 15 pieces of Protective Face Shield, type: Face shield ST001.

With regard to the fact that this is the EU type examination by a notified body, the Customer asking for assessing the conformity is responsible for selecting a sample (or prototype). The test examination does not include inspection activity focused on the conformity of properties of all products introduced to the market with the assessed (proto)type.

### 3.5 Place of performing the tests and assessment

Tests were performed in the following accredited testing laboratories: Institute for testing and certification, a.s., Zlín, Czech Republic and Meopta – optika, s.r.o., Přerov, Czech republic, Shenzhen Precision Eyewear Testing & Inspection Services Co., Ltd., China.

The documentation was examined and visual inspection and product type assessment were performed in Institute for testing and certification, a.s., Czech Republic.

### 3.6 Results of tests and assessment

Results of the personal protective equipment evaluation are summarised in Table No. 5. Test methods stated in respective part of Table No. 4 were used.

Table 5: Results of the evaluation of Protective Face Shield, type: Face shield ST001

Significant property	Measuring unit	Requirement	Determination / Document No.
General construction	-	art. 6.1 EN 166	pass / D1
Materials	-	art. 6.2 EN 166	pass / D2
Headbands	mm	art. 6.3 EN 166 > 10	pass / D4 24,7
Field of vision		art. 7.1.1 EN 166 Eye-protector shall exhibit: - minimum field of vision defined by the two ellipses in Figure 1 - placing of the ellipses shall be in compliance with requirements of standard	pass / D4 Eye protector exhibit: - larger than minimal field of vision defined by the two ellipses in figure 1 - placing of the ellipses comply with requirements of standard
<b>Optical requirements</b>			
- Spherical refractive power	m <sup>-1</sup>	art. 7.1.2.1.2 EN 166 Table 3 <b>Optical class 1:</b> ±0,06	pass / D3 <b>(optical class 1)</b> 0,00
- Astigmatic refractive power	m <sup>-1</sup>	art. 7.1.2.1.2 EN 166 Table 3 <b>Optical class 1:</b> 0,06	pass / D3 <b>(optical class 1)</b> 0,00
- Prismatic refractive power	cm/m	art. 7.1.2.1.2. EN 166 <b>Optical class 1:</b> Horizontal (base out ): max 0,75 Vertical: max 0,25	pass / D3 <b>(optical class 1)</b> Horizontal (base out): 0,15 Vertical: 0,0



Table 5: Continuation from page 9

Results of the evaluation of the Protective Face Shield, type: Face shield ST001

Significant property	Measuring unit	Requirement	Determination / Document No.
<b>Optical requirements</b>			
- Transmittance (VIS)	%	art. 7.1.2.2.1 EN 166 ≥74	<b>pass / D4</b> 87,6
- Diffusion of light	cd.m <sup>-2</sup> .lx <sup>-1</sup>	art. 7.1.2.3 EN 166 max. 0,75	<b>pass / D4</b> R / L 0,06 / 0,08
<b>Quality of material and surface</b>		art. 7.1.3 EN 166 visor shall be free from any significant defects likely to impair vision in use	<b>pass / D4</b> visor are without any significant defects likely to impair vision in use
<b>Increased robustness</b> Temperature: -5 °C / 55 °C	-	art. 7.1.4.2.2 EN 166 The following defects shall not occur: - fracture - ocular deformation - lateral protection failure	<b>pass / D5</b> Without: - ocular fracture - ocular deformation - frame deformation - defects of lateral covering
<b>Resistance to ageing</b>		-	
Stability at an elevated temperature (55 °C)	-	art. 7.1.5.1 EN 166 eye-protector shall show no apparent deformation	<b>pass / D5</b> without apparent deformation
<b>Resistance to ultraviolet radiations</b>		art. 7.1.5.2 EN 166	<b>pass / D4</b>
- Relative change of the luminous transmittance in visible spectrum	%	±5	0,50
- Diffusion of light	cd.m <sup>-2</sup> .lx <sup>-1</sup>	max. 0,75	0,07
<b>Resistance to ignition</b>	-	art. 7.1.7 EN 166 no part of eye-protector ignites or continues to glow after removal of the steel rod	<b>pass / D5</b> without ignition and continuing to glow after removal of the steel rod
<b>Marking</b>	-	art. 9 EN 166	<b>pass / D1</b>
<b>Information for users</b>		art. 10 EN 166	<b>pass / D1</b>

The bases for the evaluations stated in Table No. 5 are the test results specified in the following documents:

- D1: Record of assessment No. 723301977 issued by Institute for testing and certification, a. s. Zlín dated on 2020-08-12
- D2: Declaration about innocuousness issued by Shenzhen Stardeal Industrial Co., Ltd, China company dated on 2020-08-20
- D3: Test Report No. KX – E – 2034 issued by Meopta – optika, s.r.o., Přerov, Czech Republic on 2020-08-04
- D4: Test Report No. PL2005701 issued by Shenzhen Precision Eyewear Testing & Inspection Services Co., Ltd., China on 2020-06-03
- D5: Accredited Laboratory Test Report No. 723301977/01 issued by Institute for Testing and Certification, a.s. Zlín, Czech Republic on 2020-07-21



### **3.7 Assessment of product conformity with technical specifications and basic requirements**

The assessed product – **Protective Face Shield, type: Face shield ST001** – complies with the requirements set by the following technical standard with regard to its design and submitted documentation:

#### **EN 166:2001 Personal eye protection – Specifications**

Results of the evaluation of the personal protective equipment stated in Table No. 5 hereof prove the conformity of all indicators specifying general basic requirements of Regulation (EU) 2016/425, additional basic requirements common for more types of PPE and additional basic requirements for special risks applicable to the evaluated type of product.

### **4. Conclusion**

Notified Body 1023 performed EU Type-Examination of the personal protective equipment

#### **Protective Face Shield**

#### **Type: Face shield ST001.**

Technical specifications used by the manufacturer are in compliance with basic requirements of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.

The sample of the personal protective equipment was produced in compliance with the technical documentation of the manufacturer and can be fully safely used for its intended purpose.

The sample of the personal protective equipment meets all the provisions of the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.

Notified Body NB 1023 decided to issue the Type-Examination Certificate.

### **5. List of documents used for the preparation for the Evaluation Report**

- Application for the EU Type-Examination of Shenzhen Stardeal Industrial Co., Ltd., China company dated on 2020-06-16
- Technical documentation issued by Shenzhen Stardeal Industrial Co., Ltd., China company dated on 2020-08-31
- Check list issued by Shenzhen Stardeal Industrial Co., Ltd., China company on 2020-08-24
- Record of assessment No. 723301977 issued by Institute for testing and certification, a. s. Zlín on 2020-08-12
- Declaration about innocuousness issued by Shenzhen Stardeal Industrial Co., Ltd, China company dated on 2020-08-20
- Test Report No. KX – E – 2034 issued by Meopta – optika, s.r.o., Přerov, Czech Republic on 2020-08-04
- Test Report No. PL2005701 issued by Shenzhen Precision Eyewear Testing & Inspection Services Co., Ltd., China on 2020-06-03
- Accredited Laboratory Test Report No. 723301977/01 issued by Institute for Testing and Certification, a.s. Zlín, Czech Republic on 2020-07-21

## Face Shield Data Sheet

<b>Item Name: Protective Face Shield</b>	<b>Ref XDE200707</b>
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### 1. Photos or Drawing



### 2. International Standards

Comply with quality control and standards of GB 14866-2006, EN 166:2001, ROHS 2.0, ISO 13485:2016, etc.

### 3. Specifications

<b>Components</b>	70% PET, 20% Sponge, 8% Elastic strap, 2% Plastic buckles		
<b>Lens Dimension</b>	32×22 cm (±2mm)	<b>Lens Thickness</b>	0.25 mm (±0.02mm)
<b>Sponge Dimension</b>	25×2.8×3.5 cm (±2mm)	<b>Elastic Strap Dimension</b>	35×2.5 cm (±2mm)
<b>Applications</b>	Splash proof, Oil fume proof, Blood proof, Dust proof, etc.		

