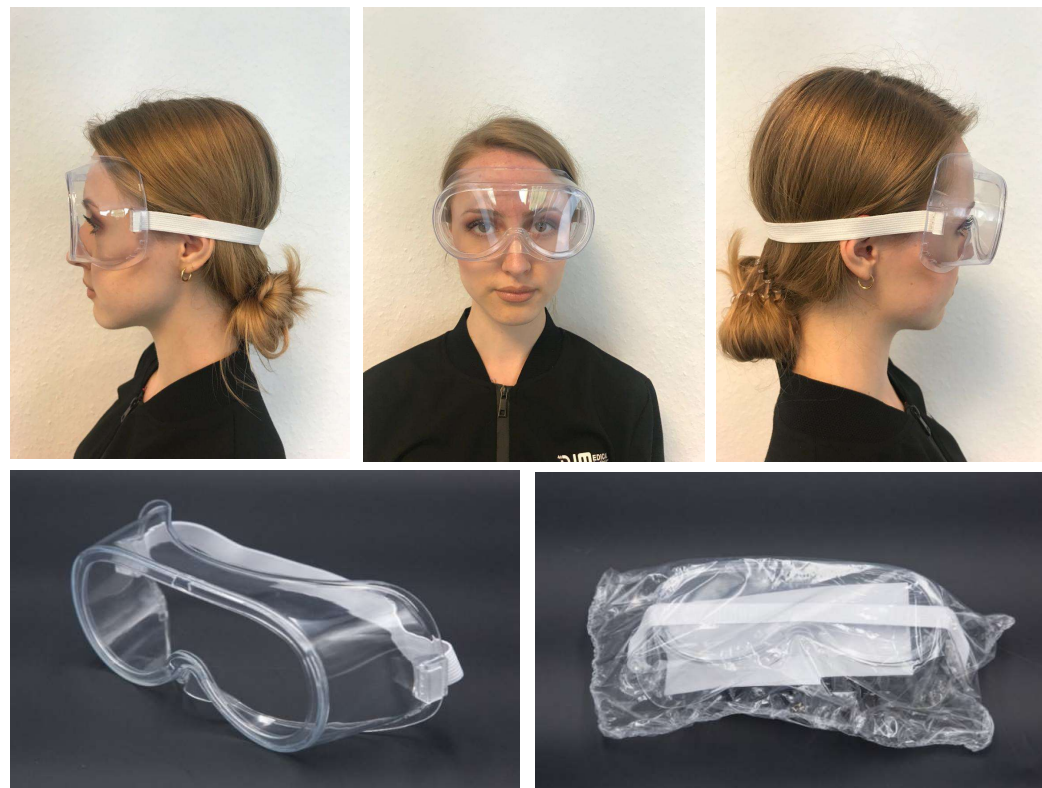


DJM Safety goggles GLYZ1-1

4.0 DJM MEDICAL
Face&Body System



Norms/Standards:	- Regulation (EU) 2016/425 - EN 166 - FDA
Product size	204*58*86 mm
Weight	51,50 g
Carton quantity	200 pcs
N.W	10,30 kg
G.W	16,50 kg
Measures	950*480*375 mm

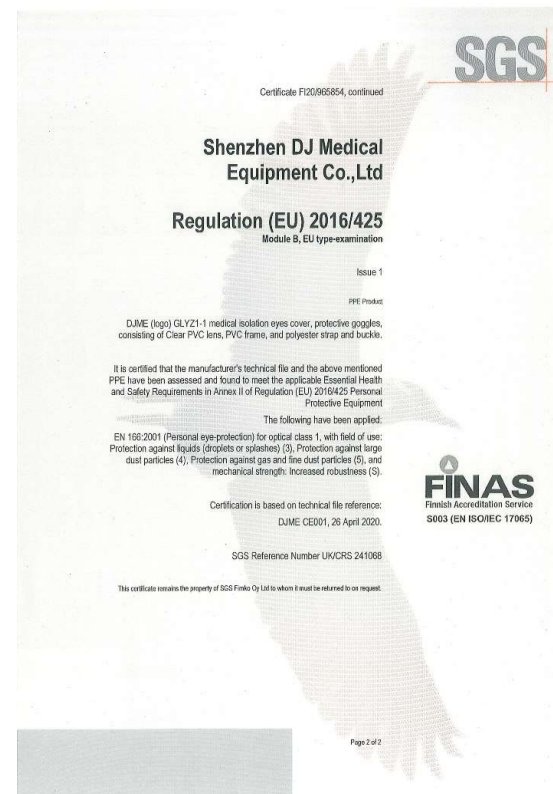


DJM Medical Instrument GmbH
Halskestr.21, 47877 Willich
Tel.: 02154 8864488, Fax: 02154 8864487
eMail: info@djmiot.com

DJM Safety goggles GLYZ1-1



Certification



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DJM Safety goggles GLYZ1-1



Certification

The screenshot shows the FDA's Establishment Registration & Device Listing page. The page header includes the U.S. Department of Health & Human Services logo and the FDA U.S. Food & Drug Administration logo. A search bar is visible with the text "Follow FDA | En Español" and a "SEARCH" button. Below the header is a navigation menu with links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The main content area is titled "Establishment Registration & Device Listing" and includes a breadcrumb trail: FDA Home > Medical Devices > Databases. A "New Search" box is present, and a "Back To Search Results" link is available. The search results display the following information:

Proprietary Name:	Isolation eyes cover, model GLYZ1-1, GLYZ1-2, GLYZ1-3; Isolation Face Mask, model GLMZ1-1
Classification Name:	ACCESSORY, SURGICAL APPAREL
Product Code:	LYU
Device Class:	1
Regulation Number:	878.4040
Medical Specialty:	General & Plastic Surgery
Registered Establishment Name:	SHENZHEN DJ MEDICAL EQUIPMENT CO.,LTD
Owner/Operator:	Shenzhen DJ Medical Equipment Co.,Ltd
Owner/Operator Number:	10067324
Establishment Operations:	Manufacturer

Page Last Updated: 04/20/2020
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

The footer contains the FDA logo, a list of links (Accessibility, Contact FDA, Careers, FDA Basics, FOIA, No FEAR Act, Nondiscrimination, Website Policies), the U.S. Food and Drug Administration address (10903 New Hampshire Avenue, Silver Spring, MD 20993, Ph. 1-888-INFO-FDA (1-888-463-6332), Contact FDA), a list of services (Combination Products, Advisory Committees, Science & Research, Regulatory Information, Safety), and the U.S. Department of Health & Human Services logo.

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DJM Safety goggles GLYZ1-2

4.0 DJM MEDICAL
Face&Body System





Norms/Standards:	- Regulation (EU) 2016/425 - EN 166: 2001
Product size	203,5*57,5*86 mm
Weight	64 g
Carton quantity	200 pcs
N.W	12,80 kg
G.W	14,18 kg
Measures	950*480*375 mm



DJM Medical Instrument GmbH
Halskestr.21, 47877 Willich
Tel.: 02154 8864488, Fax: 02154 8864487
eMail: info@djmiot.com

Certification

EU type-examination certificate


C3056.1DJME

Applicant / manufacturer	Shenzhen DJ Medical Equipment Co., Ltd. B2 Area, 5th Floor, Building C FirstFlag Science and Technology Park No. 26 Baili Road Xialiang Village Nanwan Road Longgang District SHENZHEN P.R.CHINA
Identification of the manufacturer	DJME
Product type	Eye-protectors, safety goggles for occupational use
Model name	GLYZ1-2
Standard(s) / technical rules	Essential requirements according to Annex II of the PPE-Regulation (EU) 2016/425 EN 166 : 2001
Test report(s)	1196-ECS-20 / MR 11962-ECS-20
Materials and specifications	Lenses: Polycarbonate Goggle: PVC, fabric headband Optical class 1 Protection against high speed particles, low energy impact (F) Protection against droplets of liquids (3)
Marking	DJME 1 F - 166 3 F CE


Herewith, ECS certifies that the named model complies with the essential requirements for health and safety as they are provided by the European Regulation (EU) 2016/425 for Personal Protective Equipment. This certificate is based both / either on the test results as they are summarised in the named test reports, and/or on the technical documentation as it is delivered by the manufacturer. The applicant / manufacturer agrees to the General Business Rules of the ECS GmbH and to additional agreements as they are named in the application for conformity assessment.
The eye-protection device is to be marked as assigned. Either / both the frame and/or the ocular, spectacle, goggle or shield must be signed, as appropriate. If different markings have been assessed, the lowest marking must be applied, respectively. The validity of this EU type-examination certificate will expire on the date as mentioned below, and/or if the manufacturer modifies the safety-relevant properties of this product with comparison to the tested one and/or if the requirements in the standards or technical rules will be revised and/or tightened.
Name, address and identification number 1883 of the notified body ECS are to be indicated in the information brochure of this product.

This EU type-examination certificate is valid until 2025-06.


ECS GmbH
Notified Body 1883
06/0720



Dr. Bernhard Schmitz
ECS-Certification



ECS GmbH – European Certification Service
Augenschutz und Persönliche Schutzausrüstung
Laserschutz und Optische Messtechnik
Hiltelstraße 50
73430 Aalen, Germany



Certificate of Compliance

Herewith, ECS certifies that the products

GLYZ1-2
Eye-protectors / safety goggles for occupational use

supplied by the company

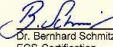
Shenzhen DJ Medical Equipment Co., Ltd.
B2 Area, 5th Floor, Building C
FirstFlag Science and Technology Park
No. 26 Baili Road
Xialiang Village
Nanwan Road
Longgang District
SHENZHEN
P.R.CHINA

comply with the essential requirements for health and safety. The product meets the requirements for optical and physical properties, luminous transmittance, diffusion of light (haze) and impact resistance as they are described in the relevant ANSI standard, respectively.


Standard / technical rules	ANSI / ISEA Z87.1 – 2020
Test report(s)	1196-ECS-20 / MR 11962-ECS-20
Optical and mechanical specifications	Clear lenses, Polycarbonate, PVC general optical and mechanical requirements protection against droplet and splash hazard
Marking	DJME Z87 D3

This certificate of compliance expires in 2025-06.
The validity of this certificate of compliance (CoC) may be compromised if the manufacturer changes the safety related properties of the product or if the Standard referred to is modified or updated.
This certificate only relates to the named test sample. Without permission of the ECS GmbH the related test report shall not be duplicated entirely or in extracts. The test report does not entitle to carry any test mark.
As a recognised and authorised testing laboratory / facility, we hereby authorise the use of our name, address and the identification number 1883 of the notified body ECS in marketing and information material produced by the manufacturer.

ECS GmbH
06/0720



Dr. Bernhard Schmitz
ECS-Certification



ECS GmbH – European Certification Service
Augenschutz und Persönliche Schutzausrüstung
Laserschutz und Optische Messtechnik
Hiltelstraße 50
73430 Aalen, Germany

Safety goggles YSA6

Norms/Standards:	- Regulation (EU) 2016/425 - EN 166: 2001
Product size	95*36*46 mm
Weight	61,40 g
Carton quantity	200 pcs
Material:	PC viewing glass PVC frame



Certification

ECS GmbH - European Certification Service

EU type-examination certificate

C3002.1LEYE

Applicant / manufacturer	Shenzhen Leye Technology Co., Ltd Room 1209, Building A Phase II of Sunshine Science & amp Technology Center Nanxin Road, Nanshan Street Nanshan District SHENZHEN CITY GUANGDONG PROVINCE P.R.CHINA
Identification of the manufacturer	LEYE
Product type	Eye-protectors, safety goggles for occupational use
Model name	leye_1 / leye_2
Standard(s) / technical rules	Essential requirements according to Annex II of the PPE-Regulation (EU) 2016/425 EN 166 : 2001
Test report(s)	1171-ECS-20 / MR 11711-ECS-20
Materials and specifications	Lenses: Polycarbonate Goggle: PVC, fabric headband Optical class 1 Increased robustness (S) Protection against droplets of liquids (3)
Marking	LEYE 1 S - 166 3 S CE

Herewith, ECS certifies that the named model complies with the essential requirements for health and safety as they are provided by the European Regulation (EU) 2016/425 for Personal Protective Equipment. This certificate is based both / either on the test results as they are summarized in the named test reports, and/or on the technical documentation as it is delivered by the manufacturer. The applicant / manufacturer agrees to the General Business Rules of the ECS GmbH and to additional agreements as they are named in the application for conformity assessment.
 The eye-protection device is to be marked as assigned. Either / both the frame and/or the ocular, spectacle, goggle or shield must be signed, as appropriate. If different markings have been assessed, the lowest marking must be applied, respectively.
 The validity of this EU type-examination certificate will expire on the date as mentioned below, and/or if the manufacturer modifies the safety-relevant properties of this product with comparison to the tested one and/or if the requirements in the standards or technical rules will be revised and/or tightened.
 Name, address and identification number 1883 of the notified body ECS are to be indicated in the information brochure of this product.

This EU type-examination certificate is valid until 2025-03.

ECS GmbH
 Notified Body 1883
 20/05/20

 Dr. Bernhard Schmitz
 ECS-Certification

ECS GmbH – European Certification Service
 Augenschutz und Persönliche Schutzausrüstung
 Laserschutz und Optische Messtechnik
 Hülfeldstraße 50
 73430 Aalen, Germany



ECS GmbH - European Certification Service
 Augenschutz und Persönliche Schutzausrüstung
 Laserschutz und Optische Messtechnik

Test Report

No. 1171-ECS-20

Contact person: Manuel Hartmann
 Phone: +49 (0)7361 9767399
 Fax: +49 (0)7361 5524254
 E-mail: manuel.hartmann@ecs-eyesafe.de
 Web: www.ecs-eyesafe.de
 Test lab accredited by DAkkS: D-PL-19590-02
 Notified by the Central Authority of the Federal States for Safety Technologies (ZLS): ZLS-NB-0304

Customer	Manufacturer
Shenzhen Leye Technology Co., Ltd Room 1209, Building A Phase II of Sunshine Science & amp Technology Center Nanxin Road, Nanshan Street Nanshan District SHENZHEN CITY GUANGDONG PROVINCE P.R.CHINA	
Test report contains	Main part and 1 measurement report
Number of pages in this test report	13
Product	Safety spectacles for occupational use
Arrival of the samples	May 08, 2020
Period of testing	May 11 – 19, 2020
Test specifications (Standards)	EN 166 : 2001, ANSI / ISEA Z87.1 – 2015
Remarks	-
The results described in this test report refer to the mentioned test samples, exclusively. A copy of the test report, complete or in extracts, is not allowed without any written permission of the ECS GmbH Aalen. Aalen, 20 May 2020	

Manuel Hartmann, B.Eng.
 ECS test engineer

Address: Hülfeldstraße 50 73430 Aalen	Geschäftsführer: Dr. Bernhard Schmitz	Registering: Uln HRB 720731	USt-IDNr: DE25376674
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DJM protective shield GLMZ1-1

4.0 DJM MEDICAL
Face&Body System



Product size	350*240*30 mm
Weight	60,70 g
Carton quantity	200 pcs
N.W	12,20 kg
G.W	13,90 kg
Measures	680*383*415 mm



Certification

TEST REPORT

Hardline Laboratory Report No. : YA50212/2020
 Page : 1 of 2
 Date : JUN. 01, 2020

Shenzhen DJM Medical Equipment Co., Ltd.
 B2 Area, 5th Floor, Building C, First Flag Science and Technology Park,
 No. 26, Baili Road, Xiaohang Village, Nanwan Road, Longgang District,
 Shenzhen, China

The following merchandise was submitted and identified by the applicant as:
Product Description: Medical isolation face mask
Style/Item No.: GLMZ1-1
Country of Origin: Chian
SGS Reference No.: SDHL20040034460T

We have tested the submitted sample(s) as requested and the following results were obtained:
Test Requested: EN ISO 12312-1:2013+A1:2015 Eye and face protection — Sunglasses and related eyewear — Part 1: Sunglasses for general use
 Clause 7.3 Impact resistance of the filter, strength level 1

Test Method & Result: --- See following sheet(s) ---

Date of Receipt: MAY 27, 2020
Testing Period: MAY 27 ~ JUN. 01, 2020
 --- See Next Page ---

Signed for and on behalf of
 SGS Taiwan Ltd.
 Owen Cheng
 Manager

Testing site:
 61, Kai-Fa Road, Nazih Export Processing Zone, N1170, Kaohsiung, Taiwan

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 (886-2) 2299-9200
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TEST REPORT

Hardline Laboratory Report No. : YA50212/2020
 Page : 2 of 2

Test Method & Result
 EN ISO 12312-1:2013+A1:2015 Eye and face protection — Sunglasses and related eyewear — Part 1: Sunglasses for general use

Clause 7.3 Impact resistance of the filter, strength level 1	Result Pass
Finding None of the following defects occurred: a) cracks through its entire thickness and across a complete diameter into two or more separate pieces, or b) a person with a visual acuity of at least 1.0 (6/6 or 20/20) can see, when viewing without magnification but wearing the appropriate correction, if any, for near vision, either a piece of material that has become detached from the filter surface or a corresponding surface defect, or c) the test ball passes through the filter. This requirement also applies to the filter portions	See Finding See Finding

Remark: 1. Samples were provided by applicant and samples were randomly selected to be assessed.
 2. The content of this report is invalid if it is not presented as the entire report.
 3. The statement of conformity is based on the test results, but does not include the measurement uncertainty.

-- Picture(s) --

Photo "A" Appearance of sample (front view) Photo "B" Appearance of sample (back view)

--- End of Report ---

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