



REFINE

EU TYPE-EXAMINATION (MODULE B) CERTIFICATE No. 2821-PPE-0003

This is to certify that UL International (Netherlands) B.V. did undertake the relevant type approval procedures for the equipment identified below which was found to be in compliance with the relevant provisions of the Personal Protective Equipment Regulation (EU) 2016/425, as amended, subject to any conditions attached hereto.

Manufacturer: Guilin Refine Medical Instrument Co., Ltd.

Address: No.8-3, Information Industrial Park, High-Tech Zone, Qixing District,

Guilin, Guangxi, 541004, P.R. China

Authorised Representative: MedPath GmbH

Address: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

Product Description: Equipment providing protection of the face and eyes; Spectacles and

Face-shield

Product Code: EP03, Model B

Harmonized Standard(s): EN 166:2001

The attached schedule of approval forms part of this certificate. This certificate remains valid unless cancelled or revoked, provided the conditions in the attached schedule are complied with and the equipment remains satisfactory in service.

Date of 1st issue: 1 May 2020

Issue: 1
Date of re-issue: N/A

Date of expiry: 1 May 2025

Issued by UL International (Netherlands) B.V., Notified Body

2821.

Signed:

Name: Horst Thelen

Head of Notified Body





(Netherlands) B.V.

Notified Body 2821

Schedule of Approval for No. 2821-PPE-0003

Date of 1st issue: 1 May 2020 Issued by: UL International

Issue: 1

Date of re-issue: N/A

Date of expiry: 1 May 2025

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EP03 Spectacles Product details:

Lens: Transparent Polycarbonate (PC)
Frames: Transparent Polycarbonate (PC)

Model B Face-shield Product details:

Lens: Transparent Polyethylene terephthalate (PET)

Foam strip: Yellow / White / Black PU Sponge

Elastic Strap: White Cloth – 20mm width (70% Polyester, 30% Rubber)

Places of production:

Guilin Refine Medical Instrument Co., Ltd.

No.8-3, Information Industrial Park, High-Tech Zone, Qixing District, Guilin, Guangxi, 541004, P.R. China

Product and Approval documentation:

Technical File Safety Spectacle PPER Technical Documentation (EP03) Version 1.4 : Face Shield

PPER Technical Documentation (Model: B) Version 1.2

Type Report NC31190-D2-European Directive-Original and Attachments

Test Reports C80272046, C8028070

Limitations on the acceptance or use of the product(s):

EP03: Spectacles (Optical Class: 1, Robustness: S, Resistance to fogging of Oculars: N)

Model B: Face-shields (Optical Class: 1, Robustness: S, Protection against Droplets and Splashes: 3, Resistance to fogging of Oculars: N)

Terms and Conditions:

- This certificate remains the property of UL International (Netherlands) B.V., herein "UL NL", and will be withdrawn if any conditions attached to its issue are not complied with.
- This certificate is issued subject to the Global Services Agreement (GSA) and PPER Service Terms.
- 3. Production is limited to the site(s) as listed, or detailed within the Technical documentation held by UL NL.
- Any product change, production/process changes, or changes in state of the art which may affect conformity shall be notified to UL NL.

END OF CERTIFICATE