



EU CERTIFICATE

EU TYPE-EXAMINATION (MODULE B) CERTIFICATE No. 2821-PPE-0002

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; Goggles and Face - shield**
Product Code: **EP01, Model A**
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: **27 April 2020**
Issue: **1**
Date of re-issue: **N/A**
Date of expiry: **27 April 2025**

Signed:

Issued by UL International (Netherlands) B.V., Notified Body 2821.

Name: **Horst Thelen**
Head of Notified Body



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Schedule of Approval for No. 2821-PPE-0002

Date of 1st issue: **27 April 2020**
Issue: **1**
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Date of expiry: **27 April 2025**

Issued by: **UL International
(Netherlands) B.V.
Notified Body 2821**

EP01

Product details:

Nosepiece: Transparent Polyvinyl chloride (PVC)
Lens: Transparent Polycarbonate (PC)
Frames: Transparent Polyvinyl chloride (PVC)
Elastic strap: Black Cloth - 20 mm width (70% Polyester, 30% Rubber)

Model A

Product details:

Lens: Transparent Polyethylene terephthalate (PET)
Frames: Blue Polycarbonate (PC)
Elastic Strap: Black 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 Goggle PPER Technical Documentation (EP01) Version 1.1 ; Face Shield PPER
Technical Documentation (A) Version 1.0
Type Report NC31190-D1-European Directive-Original and Attachments
Test Reports C80132072R001; C80202008R002

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

EP01: Goggles (Optical Class: 1, Robustness: S, Protection against Droplets and Splashes: 3, Resistance to fogging of Oculars: N)

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

Terms and Conditions:

1. This certificate remains the property of UL International (NL) B.V., herein "UL NL", and will be withdrawn if any conditions attached to its issue are not complied with.
2. 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.
4. 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