



# 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 1<sup>st</sup> 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



# EU CERTIFICATE

## Schedule of Approval for No. 2821-PPE-0002

Date of 1<sup>st</sup> issue: **27 April 2020**  
Issue: **1**  
Date of re-issue: **N/A**  
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



# EU CERTIFICATE

## 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 1<sup>st</sup> issue: **1 May 2020**  
Issue: **2**  
Date of re-issue: **11 May 2020**  
Date of expiry: **1 May 2025**

Signed:

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

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



# EU CERTIFICATE

## Schedule of Approval for No. 2821-PPE-0003

Date of 1<sup>st</sup> issue: **1 May 2020**  
Issue: **2**  
Date of re-issue: **11 May 2020**  
Date of expiry: **1 May 2025**

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

### 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, C80282070

### 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:

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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



# EU CERTIFICATE



## EU TYPE-EXAMINATION (MODULE B) CERTIFICATE No. 2821-PPE-0014

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**  
Product Code: **EP02, EP05**  
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 1<sup>st</sup> issue: **15 June 2020**  
Issue: **1**  
Date of re-issue: **N/A**  
Date of expiry: **15 June 2025**

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

Signed:

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





# EU CERTIFICATE

## Schedule of Approval for No. 2821-PPE-0014

Date of 1<sup>st</sup> issue: 15 June 2020  
Issue: 1  
Date of re-issue: N/A  
Date of expiry: 15 June 2025

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

### EP02

#### Product details:

Frames: Transparent Polyvinyl chloride (PVC)  
Lens: Transparent Polycarbonate (PC)  
Elastic Strap: Black/White Cloth - 12 mm width (70% Polyester, 30% Rubber)

### EP05

#### Product details:

Frames: Transparent Polyvinyl chloride (PVC)  
Lens: Transparent Polycarbonate (PC)  
Elastic Strap: Black/White Cloth - 12 mm width (70% Polyester, 30% Rubber)  
Plug: High Density Polyethylene(HDPE)

#### 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 RF-EP2-T001 version 1.0; RF-EP5-T001 version 1.0  
Type Report NC31190-D3-Europen Directive-Original and Attachments  
Test Reports C80602016/PL2006048; C80602017/PL2006051

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

EP02: Goggles (Optical Class: 1, Robustness: S, Protection against Droplets and Splashes: 3, Resistance to fogging of Oculars: N)

EP05: Goggles (Optical Class: 1, Robustness: S, Protection against Droplets and Splashes: 3, Resistance to fogging of Oculars: N)

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