EU DECLARATION OF CONFORMITY

No: RF-MIM-K102

1. PPE (product, type, batch or serial number):

   Face Shield, Category II, AZ541

2. Name and address of the manufacturer and authorised representative:

   Manufacturer: Guilin Refine Medical Instrument Co.,LTD.

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

   Authorised representative：MedPath GmbH

   Address of the Authorised representative：Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

3. This declaration of conformity is issued under the sole responsibility of the manufacturer:

   Guilin Refine Medical Instrument Co.,LTD.

4. Object of the declaration :

   Model B Pictrue: 

   Traceability Labeling:

   医用隔离面罩 Face Shield
   产品品牌 Brand: Refine
   型号 Model: B
   批号 Lot No.: AZ541
   生产日期 Production Date: 2020年5月 (May 2020)

5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation:

   REGULATION (EU) 2016/425

6. The notified body performed the EU type-examination (MODULE B)，and issued the certificates:

   CERTIFICATE No. 2821-PPE-0003

7. The Test Reports and references to the relevant harmonised standards used:

   Test Reports: C80282070

   EN 166:2001

8. Where applicable, the notified body

   UL International (Netherlands) B.V. European Notified Body (No. 2821)

Signed for and on behalf of Guilin Refine Medical Instrument Co.,LTD.

(place and date of issue):Guilin , 2020-05-07

(Name: Jordan Chen, Title: Management representative) signature: Jordan Chen