



# Attestation of Conformity

**No. ICR Polska/M3600010**



**Name and address  
of Registered Manufacturer:**

Quan Zhou Baili Medical Supplies Co., Ltd.  
No.1 Building, 168 Hailing Road, Zhangban Town, Taiwan  
Business Investment Zone, Quanzhou City, Fujian Province,  
China

**Product name:**

Disposable Medical Mask

**Product type/model:**

17.5cm\*9.5cm

**Trade mark:**

n/a

**This Attestation confirms that the product meets the requirements of the following normative documents and within limits of its documents gives presumption of conformity with essential requirements of Directive 93/42/EEC.**

**Relevant EC Directive:**

Medical Device Directive 93/42/EEC

**Conformity assessment  
procedure:**

EC Declaration of Conformity (Annex VII of Directive  
93/42/EEC)

**Classification:**

Class I according Rule 1 of Annex IX of Directive 93/42/EEC

**Applied normative documents:**

EN 14683:2005

**Applied Quality  
Management System**

n/a

This AoC will remain valid only if Quality Management System Certificate remains valid.  
The assessment process has been carried out in accordance with the program PC-P-07-07.  
Evaluation has been carried out in accordance with test report made by:

- Shanghai GOM Testing & Technical Co., Ltd.

**No. of test report:**

GOM200323295T

**Issue date:**

25.03.2020

**Expiration date:**

24.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR  
Polska/2020-3125.

This Attestation applies to products having the same attributes (parameters), intended use, that have  
been evaluated and meet the requirements of the aforementioned standard.



Director: Rafał Kalinowski

Warsaw, 19. 03. 2020.

**ICR Polska Co. Ltd.**

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