

# Certificate of CE-Registration

This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

Guangzhou Aquila Precise Tools Ltd.
Jinsiwei Industrial Zone
Dachongkou Village, Shawan Town, Panyu District
511483 Guangzhou City
CHINA

as stipulated and demanded by the aforementioned Directive. The German Competent Authority has allocated the medical devices of the Manufacturer registration numbers as foreseen in:

Annex A dated June 03, 2019

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the medical devices fulfill the applicable requirements of Directive 93/42/EEC. In compliance with German law, a safety officer has been appointed for Germany.

2019-06-03

Dr. Philipp Hohenbrink

Consultant MDSS GmbH







## **EC Certificate**

Full Quality Assurance System Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in class I in sterile conditions, sterilized systems or procedure packs)

No. G1S 004235 0003 Rev. 00

Manufacturer: **Guangzhou Aquila Precise Tools Limited** 

> Jinsiwei Industrial Zone Dachongkou Village Shawan Town Panyu District

511483 Guangzhou City

PEOPLE'S REPUBLIC OF CHINA

Guangzhou Aquila Precise Tools Limited Facility(ies):

Jinsiwei Industrial Zone, Dachongkou Village, Shawan Town, Panyu District, 511483 Guangzhou City, PEOPLE'S REPUBLIC

OF CHINA

Product Category(ies): **Punches** 

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex II. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

GZ1831801 Report No.:

Valid from: 2019-02-26

2019-02-26

Date,

Valid until: 2024-02-25

1. Punil

Stefan Preiß

Page 1 of 1 TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

#### Guangzhou Aquila Precise Tools Limited

### EC Declaration of Conformity

No.	TY/QWCE-039-01		
Version	Α	Revise	0

#### **EC Declaration of Conformity**

Manufacturer:
Guangzhou Aquila Precise Tools Limited.

Jinsiwei Industrial Zone, Dachongkou Village, Shawan Town, Panyu District, 511483 Guangzhou City, PEOPLE'S REPUBLIC OF CHINA whose single Authorized Representative: Medical Device Safety Service GmbH Schiffgraben 41, 30175 Hannover, Germany

We, the manufacturer, herewith declare that the product

#### **Medical Masks**

Models: A, B, C

UMDNS-Code: 12-458

meets the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark



The product concerned has been manufactured according to Annex VII of Directive 93/42/EEC.

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

The above mentioned declaration of conformity is exclusively under the responsibility of

Guangzhou Aquila Precise Tools Limited

Guangzhou City, CHINA, March 23, 2020

Place, date

General Manager
Legally binding signature, Function