



**ISET S.r.l.**

Sede Legale e Uffici  
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Cap. soc. i.v. € 10.200,00  
Cod. Fisc. e P.IVA 02 332 750 369  
Reg. Imprese 02 332 750 369  
REA MN 0221098

## CERTIFICATE OF COMPLIANCE

Certificado de Conformidade - Сертификат соответствия - Konformitätserklärung

**1) APPLICANT:**

Yuyao Rising Plastic & Hardware Factory  
No. 127 Qiaoxi, Jiangjiadu Village, Lizhou Street,  
Yuyao City, Ningbo, Zhejiang, China.

**2) CERTIFICATE NO.:**

IT061623RS170608

**TCF(S) NO.:**

TCF(17)-184-MDD

**3) WITH REFERENCE TO EC DIRECTIVE APPLIED:**

Medical Device Directive 93/42/EEC

**HARMONIZED STANDARDS APPLIED:**

EN ISO 14971:2012,  
EN 980:2008, EN 1041:2008  
EN ISO 10993-1:2009/AC:2010

**4) CERTIFICATION ISET MARK:**



**5) PRODUCT CHARACTERISTICS:** Mouthpiece

**MODEL(S):** AQ6020, Drager7410, Drager7510, Drager6510, Drager6810, Drager6810 med, Drager6820, ACE, Lion500

**REMARK:** The verification has been carried out on voluntary application of the manufacturer based only on the documents prepared and provided by the manufacturer itself. The product(s) satisfies the requirements of the Certification Mark of ISET according to the ISET regulations. The manufacturer is responsible to maintain the internal production control to ensure the compliance of the product. ISET declines any liability with reference to any other noncompliance of documents, product or test report that have been submitted to evaluation. However CE marking and EC declaration are duties of the manufacturer before putting into service of its product(s) on market as well as the verification doesn't imply assessment of the production of the product(s). The manufacturer is liable to take all the necessary actions required by the applicable directives & procedures before putting CE mark on the product(s). The manufacturer should be responsible for the results caused by improper use this verification.

**6) DATE OF ISSUE:** 08/06/2017

**DATE OF EXPIRE:** 07/06/2022

**CERTIFICATION MANAGER:**





# Certificate

Certificate No.: USA16Q23595R0S

This is to certify that the Quality Management System of

## YUYAO RISING PLASTIC HARDWARE FACTORY

Organization Code: L66713874

Registered Address: No. 127, Qiaoxi, Jiangjiadu Village, Lizhou Street, Yuyao

Production/Office Address: No. 127, Qiaoxi, Jiangjiadu Village, Lizhou Street, Yuyao, Zhejiang, China

Has been audited to conform to the following Quality Management System standard

### ISO 9001:2008

This Quality Management System is valid for the  
Manufacture of hardware parts, plastic parts  
(except licensing requirements)

Initial issued date: Jun. 22, 2020

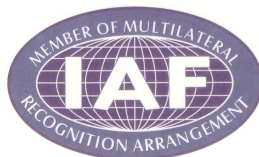
Date of issue: Jun. 22, 2020

Date of expiry: Sep. 15, 2022

Issued by: *Wu Fengru*



Beijing East Allreach Certification Center Co., Ltd.



This certificate will remain valid only if the certified organization accepts at least one surveillance audit annually within the validity period of the certificate and the surveillance audit conforming mark is in the designated position on the certificate. The information of this certificate is available at EACC website [www.eacc.com.cn](http://www.eacc.com.cn) and CNCA website [www.cnca.gov.cn](http://www.cnca.gov.cn).

EACC address: 1st Floor, No. 121 building, No. 17, Jingshengnansi Street, Jinqiao Science & Technology Industrial Base, Tongzhou Park of Zhongguancun Science & Technology Zone, Tongzhou District, Beijing 101102

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