



ISET S.r.l.

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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 improperly use this verification.

6) DATE OF ISSUE: 08/06/2017

DATE OF EXPIRE: 07/06/2022

CERTIFICATION MANAGER:

