

ISET s.r.l.

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CERTIFICATE OF COMPLIANCE

Certificado de Conformidade - Сертификат соответствия - Konformit ätserkl ärung

1) APPLICANT:

Suzhou Heaven Wind Environmental Technology Co.,Ltd Qiushe Industrial Zone,ongli Town,Wujiang,Suzhou City, Jiangsu Province,China

2) CERTIFICATE NO.: IT020931HW160919

TCF(S) NO.: TCF(16)-531-MDD

3) WITH REFERENCE TO EC DIRECTIVE APPLIED:

Medical Device Directive 93/42/EEC

HARMONIZED STANDARDS APPLIED:

EN ISO 14971:2012 EN ISO 10993-1:2009/AC:2010 EN 980:2008 4) CERTIFICATION ISET MARK:



5) PRODUCT CHARACTERISTICS: Hospital Disposable Curtain

MODEL(S): Length:1M-15M, Height:1M-3M, For example:7.5*2M=Length*Height

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 marking and EC declaration are duties of the manufacturer before putting into service of its product(s) on market. The manufacturer is liable to take all the necessary actions required by the applicable directives&procedures.

6) DATE OF ISSUE: 19/09/2016 DATE OF EXPIRE: 18/09/2021

CERTIFICATION MANAGER. ISET S.R.L. STITUTO SERVICE ISET S.R.L. OS PORE TECNOLOGY