



ISET S.r.l.

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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:

Hengshui Hengzekang Medical Equipment Co. Ltd
Dafenglin Village, Guangchuan Town, Jing County,
Hebei Province, China

2) CERTIFICATE NO.:

IT091606HK160824

TCF(S) NO.:

TCF(16)HHME-20160819-MDD

3) WITH REFERENCE TO EC DIRECTIVE APPLIED:

Medical Device Directive 93/42/EEC

HARMONIZED STANDARDS APPLIED:

EN 60601-2-52:2010/AC:2011

4) CERTIFICATION ISET MARK:



5) PRODUCT CHARACTERISTICS: Manual Nursing Bed

MODEL(S): E05/E07/E08/E21/E22/E23/E25/E28/E29/E34/E35/M11/M12/M14/M16/M18/M19/M22/M23/M26

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. The manufacturer is required to appoint a Notified Body to get the CE Certification and meet all the necessary law requirements according to the Directive and accepted by the Notified Body.

6) DATE OF ISSUE: 24/08/2016

DATE OF EXPIRE: 23/08/2021

CERTIFICATION MANAGER:



Nguyễn Phan Quý
0938.062.808