



Heal Force

Heal Force Bio-Meditech Holdings Group
Shanghai Lishen Scientific Equipment Co.,Ltd

No. 6788, Songze Street, Qingpu Dist, Shanghai. P. R. China

Declaration of conformity

Product: Electric Operating Table

Type: HFease-400, EST-I

Product classification: Class I

The submitted sample of the above product has been tested by SGS-CSTC Standards Technical Services (Shanghai) Co.,Ltd for CE marking according to the related European Directives

93/42/EEC Medical Device Directive (including 2007/47/EC)

Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

Standard(s): EN ISO 14971:2009; EN980:2008; EN1041:2008
EN 60601-1:2005+CORR.1:2006+CORR.2:2007+AMI:2012
EN 60601-1-2:2007+AC:2010
EN 60601-2-46: 2010 (Second edition) for use in conjunction
with IEC60601-1:2005 (Third edition)
EN ISO 14155-1:2003; EN ISO 14155-2:2003; ISO 13485:2003

The technical documentation of the listed devices is in conformity with the requirements.
The review result of the technical files and test report support the self- declaration for the devices listed above.

The test report and technical files are the annex of this report should be used together.

Mar 30th, 2017

Mr. Bill Shum

General Manager

Shanghai Lishen Scientific Equipment Co., Ltd

