

Declaration of Conformity

For the following products:

Transcutaneous Electrical Nerve Stimulation

(Product Name)

XTR4 , EMP 4ECO+

(Model Designation)

is hereinafter confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive(93/42/EEC As amended by 2007/47/EC)

EN ISO14971 : 2009

EN60601-1:1990+A1:1993+A2:1995

EN60601-1-2:2001+A1:2006

EN60601-1-4:1996+A1:1999

EN60601-2-10:2000+A1:2001

EN980:2008

EN1041:2008

ISO10993-1:2009

EN62304:2006

The following representative in Europe is responsible for making this declaration:

Company Name: *MONATH ELECTRONIC E.U.R.L.*

Company Address: *28, rue Maréchal Joffre F-68250 ROUFFACH FRANCE*

The following manufacturer is responsible for making this declaration:

Company Name: *Wuxi Jiajian Medical Instrument Co., Ltd.*

Company Address: *Qinghong Rd. Ehu Town, Xishan District, Wuxi City, China*

总经理请签名

General Manager

日期

Wang Wengying

General Manager

2011.10.28

(Legal Signature)

(Position/title)

(Date)