

Declaration of Conformity

For the following products:

Sterile Surgical Blade and Disposable Scalpel

(Product Name)

9#, 10#, 11#, 12#, 15#, 15c#, 17#, 18#, 19#, 20#, 21#, 22#, 23#, 24#, 24d, 25#, 34#, 36#

(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 ISO14971:2007, EN980:2008, □□
ISO9001:2008, ISO13485:2003, ISO14971:2007, EN980:2008, ISO7135-1:1991and Amendment1-1999,
ISO11137-1:2006 , ISO7440-1998, EN1041:2008, ISO10993:2003, ISO11607-1:2006

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

Company Name: CHEMIL s.r.l

Company Address: Via Canada 23 - 35127 Padua

The following manufacturer is responsible for making this declaration:

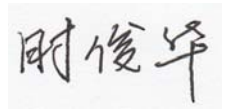
Company Name: Suzhou Kyuan Medical Apparatus Co., Ltd.

Company Address: Beiqiao Town, Suzhou City, P.R.China

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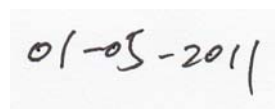
General Manager

□□



(Legal Signature)

(Position/title)



(Date)