Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlin, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 12 0434 QS/NB

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the product – medical device of Class IIa, models

Derma Needling System

Models: Dermapen needle-0.25; Dermapen needle-2.5

manufactured by company

Equipmed.
The Park, 1/5 Talavera Road, Macquarie Park 2113, NSW Australia

are manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2. of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3. and 5., of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803601527/2012, which is enclosed to this Certificate.

Condition of this Certificate use and related information:

1. *It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the **30th May 2017** at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:*

CE 1023

Issued in Zlín, on 31st May 2012

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

CE

No:SWT-1206

Declaration Of Conformity

Manufacturer : Equipmed

Unit 1/5 Talavera Road. Macquarie Park, NSW, Australia 2113

Product : **AUTO-MTS System**
Brand / Model : **Dermapen**
Classification : **Class IIa according to Annex IX**
Conformity Assessment Route : Annex V of Directive 93/42/EEC

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices amended by Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer.

Standard Applied : EN 980:2008, EN ISO 14971:2009, EN 11137-1:2006,
EN 11607-1:2006, EN 14155:2009, EN ISO 13485:2003,
EN ISO 10993-1(2009)/5(2009)/11(2009), EN556-1:2001

Notified Body : ITC NB1023

Test Lab. : S&G BioTech Inc.

Start of CE-marking : December 30, 2011 (Serial No : SWT-111201)

Place, Date of issue : Sydney / May 31, 2012

Equipmed

J. S. Choi

President J. S. CHOI

Choe Jongsu/ President