EC Declaration of Conformity

For the following products:

(Product Name)

Sterile and Non-Sterile Inner-Cavity Medical Stents and Introducer System;

a. Medical Stent with repositioning threads;

b. Nitinol Alloy Thermal-Memory Inner-Cavity Medical Stent;

c. Covered Alloy Thermal-Memory Inner-Cavity Medical Stent;

d. Medical Stent with introducer System;

e. Introducer.

(Model Designation)

Stent : Esophageal Stent/ Biliary Stent/ Intestinal Stent /Trachea and Bronchial Stents

Introducer: 24 Fr /21 Fr/ 18 Fr /16 Fr /12 Fr /10 Fr /9 Fr /8 Fr /7 Fr/ 6Fr

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)

EN1041:2008 + A1 : 2013, EN ISO 10993-1：2009/AC：2010, EN ISO 10993-3:2009, EN ISO 10993-5:2009, EN ISO 10993-6:2009, EN ISO 10993-7：2009,EN ISO 10993-10:2010, EN ISO 11135-1:2007, EN ISO 11737-1:2006/AC:2009, EN ISO 11737-2:2009,EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 14630：2009,EN ISO 13485:2012, EN ISO 14971:2012 EN ISO 15223-1：2012

Conformity Assessment Route:

Annex II excl. section 4 of Medical Device Directive

Notified Body: Det Norske Veritas Certification AS (NB No. 0434)
Veritasveien 1, 1322 Høvik, Norway

Certificate No.: 100256-2011-CE-RGC-NA Rev.1.0

Issue date: 2016-08-31 Expiry date:2021-08-31

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

Company Name: Wellkang Ltd

Company Address: Suite B, 29 Harley Street LONDON W1G 9QR, England, United Kingdom

The following manufacturer is responsible for making this declaration:

Company Name: Changzhou New District Garson Medical Stent Apparatus Co., Ltd

Company Address: No.6, Huanbao 8 Road, Huanbao Industry Zone, New District, Changzhou , Jiangsu , P.R. China

General Manager

(Legal Signature) (Position/title) 2016.8.31 (Date)

SOCIETATEA COMERCIALĂ TECMED PLUS S.R.L. BUCUREȘTI-ROMÂNIA

CONFORM CU ORIGINALUL

Declaratie de Conformitate CE

Pentru urmatoarele produse:

(Numele produselor)

Stenturi medicale si sisteme de introducere sterile si ne-sterile pentru cavitati interne:

a. Stent medical cu fire de repozitionare
b. Stent medical pentru cavitati interne cu memorare termica din aliaj Nitinol
c. Stent medical pentru cavitati interne cu memorare termica din aliaj, acoperit
d. Stent medical cu sistem de introducere
e. Introducator

(Denumirea modelelor)

Stent: Stent Esofageal/ Stent Biliar/ Stent Intestinal/ Stent Traheal si Bronhic
Introducator: 24 Fr/ 21 Fr/ 18 Fr/ 16 Fr/ 12 Fr/ 10 Fr/ 9 Fr/ 8 Fr/ 7 Fr/ 6 Fr

Prin aceasta se confirma conformitatea cu cerintele stabilite in Directivele Consiliului privind armonizarea legislatiei statelor membre referitoare la Directivele pentru Dispozitive Medicale (93/42/EEC actualizate cu 2007/47/EC)

EN 1041:2008 + A1:2013, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-3:2009, EN ISO 10993-5:2009, EN ISO 10993-6:2009, EN ISO 10993-7:2009, EN ISO 10993-10:2010, EN ISO 11135-1:2007, EN ISO 11737-1:2006/AC:2009, EN ISO 11737-2:2009, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 14630:2009, EN ISO 13485:2012, EN ISO 14971:2012, EN ISO 15223-1:2012

Calea de afirmare a conformitatii:
Anexa II sectiunea 4 a Directivei pentru Dispozitive Medicale

Entitatea notificata: Det Norske Veritas Certification AS (NB Nr.0434)
Veritasveien 1, 1322 Hovik, Norway

Certificat Nr. 100256-2011-CE-RGC-NA Rev.1.0
Data emiterii: 31-Aug-2016 Data expirarii: 31-Aug-2021

Reprezentanta Europeana responsabila pentru declaratie:
Numele companiei: Wellkang Ltd
Adresa: Suite B, Harley Street
LONDON WIG 9QR
England, United Kingdom

Producatorul responsabil pentru aceasta declaratie:
Numele companiei: Changzou New District Garson Medical Stent Apparatus Co., Ltd
Adresa: No.6, Huanbao 8 Road, Huanbao Industry Zone, New District, Changzhou, Jiangsu, P.R. China

(semnatura legala) Director General Data: 31-Aug-2016

SOCIETATEA COMERCIALA TECMED PLUS S.R.L. BUCURESTI-ROMANIA