

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 Hovik, 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

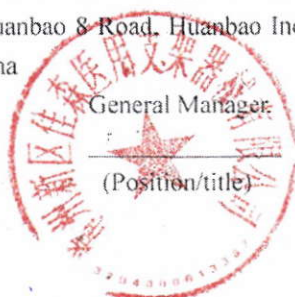
Company Address: Suite B, 29 Harley Street LONDON W1G 9QR, England, United Kingdom

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


(Legal Signature)



2016.8.31
(Date)

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 repositionare
- 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 W1G 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

