Certificate KR01/52688

The management system of

Taewoong Medical Co., Ltd.

14 Gojeong-ro, Wolgot-myeon, Gimpo-si, Gyeonggi-do, Korea

has been assessed and certified as meeting the requirements of

ISO 9001:2008

For the following activities

The scope of registration appears on page 2 of this certificate.

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2008 requirements may be obtained by consulting the organisation

This certificate is valid from 14 August 2016 until 14 September 2018 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 14 September 2018
Issue 21. Certified since 18 June 2001

Authorised by

SGS United Kingdom Ltd Certification and Business Enhancement
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

UKAS MANAGEMENT SYSTEMS
0005

SGS 9001-8 01 0216 M2

Taewoong Medical Co., Ltd.

ISO 9001:2008

Issue 21

Detailed scope

Design and manufacture of sterile biliary, oesophageal, enteral colonic, urinary, tracheobronchial and pyloric/duodenal stents system, sterile micro catheter, biopsy forceps and stent delivery systems, Sterile Single use stent remover, Sterile single use blood compression bandage, Sterile single use stone basket, Sterile single use biopsy electrode, Sterile single-use retrieval snare, Sterile single-use ENBD catheter, Sterile single-use Guidewire and Sterile single use endoscopic sclerotherapy injector .

Provision of ethylene oxide sterilization service to customer specified requirements including where specified applicable requirements of ISO 11135-1:2007.

Further Clarifications regarding the scope of this certificate and the applicability of ISO 9001:2008 requirements may be obtained by consulting the organisation

UKAS MANAGEMENT SYSTEMS
0005

Certificate KR01/52687

The management system of

Taewoong Medical Co., Ltd.

14 Gojeong-ro, Wolgot-myeon, Gimpo-si, Gyeonggi-do, Korea

has been assessed and certified as meeting the requirements of

ISO 13485:2003
EN ISO 13485:2012

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 14 August 2016 until 31 March 2019 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 31 March 2019
Issue 21. Certified since 18 June 2001

Authorised by

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

UKAS MANAGEMENT SYSTEMS
0005

Taewoong Medical Co., Ltd.

ISO 13485:2003
EN ISO 13485:2012

Issue 21

Detailed scope

Design and manufacture of sterile biliary, oesophageal, enteral colonic, urinary, tracheobronchial and pyloric/duodenal stents system, sterile micro catheter, biopsy forceps and stent delivery systems, Sterile Single use stent remover, Sterile single use blood compression bandage, Sterile single use stone basket, Sterile single use biopsy electrode, Sterile single-use retrieval snare, Sterile single-use ENBD catheter, Sterile single-use Guidewire and Sterile single use endoscopic sclerotherapy injector.

Provision of ethylene oxide sterilization service to customer specified requirements including where specified applicable requirements of ISO 11135-1:2007.

UKAS MANAGEMENT SYSTEMS
0005

Certificate KR07/4068

The management system of

Taewoong Medical Co., Ltd.

14 Gojeong-ro, Wolgot-myeon, Gimpo-si, Gyeonggi-do, Korea

has been assessed and certified as meeting the requirements of

ISO 13485:2003

For the following activities

Design and manufacture of sterile biliary, oesophageal, enteral colonic, urinary, tracheobronchial and pyloric/duodenal stents system, biopsy forceps, stent delivery systems, stone basket, Sterile single use biopsy electrode, Sterile single-use retrieval snare, Sterile single-use ENBD catheter, Sterile single-use Guidewire and endoscopic sclerotherapy injector.

Effective Date 11 August 2016 Expiry Date 31 December 2018
Re certification audit due before 31 December 2018
Valid subject to satisfactory surveillance audits.
Issue 12. Certified since 11 June 2007

Authorised by
Jan Saunders – Business Manager

SCC Accredited CB-MS OCSM Accrédité CCN TM

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com
CMDCAS recognised registrar

SGS 13485 CMDCAS 0311

EC Certificate Full Quality Assurance System: Certificate KR01/52686

The management system of

Taewoong Medical Co., Ltd.

14 Gojeong-ro, Wolgot-myeon, Gimpo-si, Gyeonggi-do, Korea

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 14 August 2016 until 14 August 2021 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 30 June 2019
Issue 29. Certified since 18 June 2001

Certification is based on reports numbered WW/PCI 201809

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M3

Taewoong Medical Co., Ltd.

Directive 93/42/EEC

**on medical devices, Annex II (excluding Section 4)
for class IIa, IIb & III**

Issue 29

Detailed scope

Covered model of

- Sterile Niti-S and ComVi Biliary Stents System;

- Sterile Niti-S and ComVi Oesophageal Stents System;

- Sterile Niti-S Tracheobronchial Stents System;

- Sterile Niti-S and ComVi Pyloric/ Duodenal Stents System;

- Sterile Niti-S and ComVi Enteral Colonic Stents System;

- Sterile Niti-S Nagi™ Stents System for pancreatic pseudocyst drainage;

- Sterile UVENTA™ Ureteral Stents System;

- Sterile UVENTA™ Urethral Stents System;

- Sterile Niti-S SPAXUS™ Stents System for drainage of pancreatic pseudocyst;

Uncovered model of

- Sterile Niti-S Biliary Stents System;

- Sterile Niti-S Oesophageal Stents System;

- Sterile Niti-S Tracheobronchial Stents System;

- Sterile Niti-S Pyloric/Duodenal Stents System;

- Sterile Niti-S Enteral Colonic Stents System;

Sterile Single-use Micro Catheter;

Sterile Single-use Biopsy Forceps (Optimos™ Biopsy Forceps);

Sterile Single-use stent remover (Optimos™ Retrieval Hook);

Sterile Single-use endoscopic sclerotherapy injector (Optimos™ Injector);

Sterile single-use biopsy electrode (Optimos™ Polypectomy Snare);

Sterile single-use retrieval snare (Optimos™ Retrieval Snare);

Sterile single-use ENBD catheter (Optimos™ ENBD Catheter);

Sterile single-use Guidewire (Optimos™ Guidewire);

Sterile single-use stone basket (Optimos™ Stone Basket).

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

EC Certificate Production Quality Assurance System: Certificate
KR12/01828

The management system of

Taewoong Medical Co., Ltd.

14 Gojeong-ro, Wolgot-myeon, Gimpo-si, Gyeonggi-do, Korea

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V
Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.

For the following products

Sterile single-use blood compression bandage (Xpress)

This certificate is valid from 14 August 2016 until 14 August 2021 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 30 June 2019
Issue 7. Certified since 10 May 2012

Certification is based on reports numbered WW/PCI 201809

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
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SGS CE 18 0811