EC Certificate Full Quality Assurance System: Certificate KR19/81826260

The management system of

Taewoong Medical Co., Ltd.

14, Gojeong-ro, Wolgot-myeon, Goyang-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 16 December 2019 until 25 March 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 18 June 2001
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered WW/PCI 201809

Authorised by

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Taewoong Medical Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 1

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™ Stent and Niti-S Hot NagiTM Stent & Electrocautery Stent Delivery System for drainage of pancreatic pseudocyst;
- Sterile UVENTA™ Ureteral Stents System;
- Sterile UVENTA™ Urethral Stents System;
- Sterile Niti-S SPAXUS™ Stent and Niti-S Hot SPAXUS™ Stent & Electrocautery Stents System for drainage of pancreatic pseudocysts;

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 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 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.

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