EC Certificate Full Quality Assurance System: Certificate KR19/81826303

The management system of

Jeil Medical Corporation

702•703•704•705•706•804•805•807•812•815-ho, 55,
Digital-ro 34-gil, Gurogu, Seoul, 08378, 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 27 March 2020 until 18 September 2023
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 30 December 2002
and first certified by SGS Belgium NV since 16 December 2019

This is a multi-site certification.
Additional site details are listed on subsequent pages

Certification is based on reports numbered WW/PCI 208304

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Jeil Medical Corporation

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 2

Detailed scope

Non-sterile bone plates and screws for oral applications.

Non-sterile bone plates and screws for oral and maxillofacial applications.

Non-sterile bone plates and screws for cranial skeleton applications

Non-sterile bone plates and screws for orthodontic applications

Non-sterile GBR bone plate and screw kit for oral cavity.

Sterile bone plates and screws for thoracic applications.

Sterile cranial skeleton bone plate and screw (Sterile NS Kit).

Sterile bone screws for orthodontic applications.

Non-sterile distractor for craniofacial bone.

Non-sterile powered drill bits for Neurosurgery, Orthopedic Surgery, Dental and Oral & Maxillofacial Surgery;

Non-sterile battery powered dental handpiece (Model: 111-ED-010, 111-ED-040)

Sterile single use battery powered surgical handpiece for Neurosurgery and Orthopedic Surgery (Model : 111-ED-030, 111-ED-031, 111-ED-050, 111-ED-051, 111-ED-052);

Sterile dental burs.

(Metrological aspects only) - Restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements;

Measuring surgical instruments for orthopedi oral & maxillofacial and cranial skeleton application

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.

Additional facilities

380, Beoman-ro, Siheung-si, Gyeonggi-do, 14928, Korea