EC Certificate Full Quality Assurance System: KR02/58135

The management system of

Jeil Medical Corporation

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Seoul,152-728, 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 2 May 2017 until 18 September 2020 and
remains valid subject to satisfactory surveillance audits.
Re certification audit due before 27 March 2018
Issue 27. Certified since 30 December 2002

Certification is based on reports numbered WW/PCI-208304

Authorised by

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Jeil Medical Corporation

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 27

Detailed scope

Non-sterile bone screws for orthopedic, oral and maxillofacial, cranial skeleton and orthodontic applications.

Sterile bone screws for orthodontic applications.

Non-sterile bone plates for orthopedic, oral and maxillofacial, cranial skeleton and orthodontic applications.

Powered drill bits for Neurosurgery, Orthopedic Surgery, Dental and Oral & Maxillofacial Surgery;

Sterile dental burs.

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

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

Non-sterile distractor for mandible and oral bone.

Non-sterile distractor for craniofacial bone.

Sterile bone plates and screws for thoracic applications.

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

Measuring surgical instruments for orthopedic, oral & maxillofacial and cranial skeleton applications.

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