

Certificate KR02/58134

The management system of

Jeil Medical Corporation

SGS

[HO & Factory 1] 702•703•704•705•706•707•804•805•807•812•815-ho, 55, Digital-ro 34-gil, Guro-gu, Seoul, 08378, Republic of Korea

has been assessed and certified as meeting the requirements of

ISO 13485:2016

EN ISO 13485:2016

For the following activities

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 31 January 2025 until 10 February 2028 and remains valid subject to satisfactory surveillance audits.

Issue 31. Certified since 30 December 2002

Certified activities performed by additional sites are listed on subsequent pages.

L. Moran

Authorised by

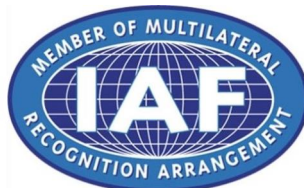
Liz Moran

Business Manager

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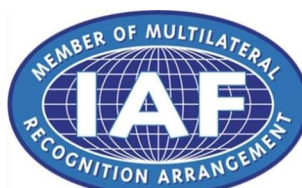
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ISO 13485:2016 EN ISO 13485:2016

Issue 31

Design and manufacture of non-sterile bone screws and plates for orthopedic, cranial skeleton and orthodontic applications.
Design and manufacture of sterile and non-sterile bone screw and plate for oral and maxillofacial.
Design and manufacture of sterile bone screws for orthodontic applications.
Design and manufacture of surgical instruments for orthopedic, oral and maxillofacial, cranial skeleton and orthodontic applications.
Design and manufacture of non-sterile powered drill bits for Neurosurgery, Orthopedic Surgery, Dental and Oral & Maxillofacial Surgery.
Design and manufacture of sterile speedy flap cranioplasty plate.
Design and manufacture of non-sterile battery powered dental handpiece.
Design and manufacture of sterile dental burs.
Design and manufacture of sterile single use battery powered surgical handpiece for Neurosurgery and Orthopedic Surgery.
Design and manufacture of sterile cranial skeleton bone plate and screw.
Design and manufacture of non-sterile GBR bone plate and screw kit for oral cavity.
Design and manufacture of non-sterile distractor for mandible, oral and craniofacial bone.
Design and manufacture of non-sterile and sterile bone plates and screws for thoracic applications.
Design and manufacture of sterile and non-sterile spine interbody fusion cage.
Design and manufacture of non-sterile Spinal Fixation System.



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ISO 13485:2016

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Issue 31

Sites

Jeil Medical Corporation

[HO & Factory 1] 702•703•704•705•706•707•804•805•807•812•815-ho, 55, Digital-ro 34-gil, Guro-gu, Seoul, 08378, Republic of Korea

Design and manufacture of non-sterile bone screws and plates for orthopedic, cranial skeleton and orthodontic applications.

Design and manufacture of sterile and non-sterile bone screw and plate for oral and maxillofacial.

Design and manufacture of sterile bone screws for orthodontic applications.

Design and manufacture of surgical instruments for orthopedic, oral and maxillofacial, cranial skeleton and orthodontic applications.

Design and manufacture of non-sterile powered drill bits for Neurosurgery, Orthopedic Surgery, Dental and Oral & Maxillofacial Surgery.

Design and manufacture of sterile speedy flap cranioplasty plate.

Design and manufacture of non-sterile battery powered dental handpiece.

Design and manufacture of sterile dental burs.

Design and manufacture of sterile single use battery powered surgical handpiece for Neurosurgery and Orthopedic Surgery.

Design and manufacture of sterile cranial skeleton bone plate and screw.

Design and manufacture of non-sterile GBR bone plate and screw kit for oral cavity.

Design and manufacture of non-sterile distractor for mandible, oral and craniofacial bone.

Design and manufacture of non-sterile and sterile bone plates and screws for thoracic applications.

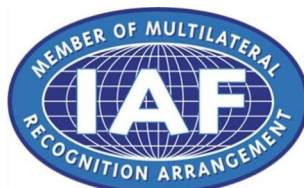
Design and manufacture of sterile and non-sterile spine interbody fusion cage.

Design and manufacture of non-sterile Spinal Fixation System.

Jeil Medical Corporation

[Factory 2] 380, Beoman-ro, Siheung-si, Gyeonggi-do, 14928, Republic of Korea

Machining & surface treatment process in support of design and manufacture of bone screws, plates and fusion cages.



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