



## Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that:

Seawon Meditech Co., Ltd. 33, Bucheon-ro 298 beon-gil Wonmi-gu Bucheon-si Gyeonggi-do 420-803 Republic of Korea

Holds Certificate No:

MD 549719

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

The manufacture of sterile Inflatable bone expander system that is composed of Balloon Catheter, Balloon Expander and Bone Cement Dispenser. The manufacture of sterile bone extractor. The design and manufacture of Epidural Catheter and Accessory. The manufacture of Platelet-Rich Plasma(PRP) collection device. The design and manufacture of Electrosurgical Cutting and Coagulation Device(for ablation, coagulation, and decompression to treat herniated discs). The manufacture of cervical traction device. The manufacture of bone marrow biopsy needles.

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For and on behalf of BSI:

Frank Lee, EMEA Compliance & Risk Director

Original Registration Date: 03/06/2009 Latest Revision Date: 26/05/2015 Effective Date: 03/06/2015 Expiry Date: 02/06/2018

Page: 1 of 1



...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory or telephone +82 2 777 4123.

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