By Royal Charter

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.

For and on behalf of BSI:

Frank Lee, EMEA Compliance & Risk Director

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

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