EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 549721**

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

In respect of:

The design and manufacture of sterile SPASYTM balloon expander, balloon catheters, bone marrow needles, guide wire, sterile cannula, bone drill, bone cement filler, sterile SPASYTM bone cement dispensing, bone extractor devices, Epidural Catheter and Platelet-Rich Plasma (PRP)collection device.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **24 June 2009** Date: **03 July 2015** Expiry Date: **23 June 2019**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 549721**
Date:	**03 July 2015**
Issued To:	**Seawon Meditech Co., Ltd.** **33, Bucheon-ro 298 beon-gil** **Wonmi-gu** **Bucheon-si** **Gyeonggi-do** **420-803** **Republic of Korea**

Subcontractor:	**Service(s) supplied**
Nischem Medical Co. Ltd. #212, Ijeon-ri Bogae-myeon Anseong-si Gyeonggi-do 456-873 Republic of Korea	**ETO Sterilization**
Tecnica Scientifica Service S.r.l Via Bologna 220 Torino, TO 10154 Italy	**EU Representative**

...making excellence a habit.™

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 549721**

Date: **03 July 2015**

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

Date	Reference Number	Action
24 June 2009	7388368	First Issue
28 October 2010	7519524	Additional product 'bone extractor devices'. Scope clarification to include accessories which were covered by initial review. Removal of S&G Biotech as a sterilization subcontractor, and addition of Taewoong Medical Co., Ltd as an ETO sterilization subcontractor.
30 January 2012	7633815	Upgrade of certificate from Annex V, Section 3.2 to Annex II, Section 3.2. Extension to scope to include, "design" and "Epidural Catheter". Removal of significant subcontractor Taewoong Medical Co., Ltd. Addition of significant subcontractor Nischem Medical Co. Ltd for ETO sterilization activities.
06 March 2013	7959941	Change of client and EC Rep addresses
07 August 2013	7946195	Scope extension
12 June 2014	8166134	Certificate Renewal
07 August 2014	8197061	Change of scope: "cannula" to "sterile cannula".
03 July 2015	8360396	Change of EU Rep to: 'Tecnica Scientifica Service S.r.l, Via Bologna 220, 10154 Torino, TO, Italy'