Quality System Approval Certificate

Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 252 of 1994)*

APPROVES THE QUALITY SYSTEM APPLIED BY

Medspira LLC

2718 Summer Street NE
Minneapolis
MN 55413
USA

to the Product Family

RF MRI system coil
(BC-10)

on the basis of examination under the requirements of Annex II, Section 3.2 of Directive 93/42/EEC.
*The use of the NSAI Notified Body identification number **0050** in conjunction with CE Marking of Conformance for this product family is hereby authorised.*

Registration Number:	**252.917**
Original Approval:	**31 October 2013**
Last Amended on:	**31 October 2013**
Remains valid until:	**30 October 2016**

Signed:

Approved by:
Kevin D. Mullaney
Chief Executive Officer - NSAI Inc.

Approved by:
John O'Dwyer
European manager

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner .
Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.