



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

Sheathing Technologies, Inc.

18431 Technology Drive
Morgan Hill
CA 95037
USA

to the Product Family

SHEATHES - Sterile Extended-Field Ultrasound Probe Covers & Accessories

*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:	252.811
Original Approval:	03 August 2010
Last Amended on:	03 August 2010
Remains valid until:	02 August 2013

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.