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.

675 Jarvis Drive
Morgan Hill
CA 95037
USA

to the Product Family

Sheathes - Sterile Latex & Sterile Latex-Free Ultrasound Probe Covers, accessories and Sterile Ultrasound Coupling Gel

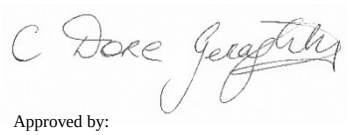
GMDN Code: 60608, 44713 60609, 44714, 58735

on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices, Annex II, excluding (4)

*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:	**28 October 2020**
Remains valid until:	**26 May 2024**

Signed:



Approved by:
Dr. Caroline Dore Geraghty
Director, Medical Devices

Approved by:
Dr. Elaine Darcy
European Medical Device Operations Manager

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

In the case of a Class III device, this certificate must be supported by a valid design examination certificate

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