



NSAI

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

Surgical Concepts, Inc.

4919 Warrensville Center Road
Cleveland
OH 44128
USA

to the Product Family

Sterile Adhesive Wire, Tubing and Instrument Organizer

GMDN Code: 56630

*on the basis of examination under the requirements of Annex II, Section 3 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:	252.963
Original Approval:	28 July 2015
Last Amended on:	28 July 2015
Remains valid until:	27 July 2018

Signed:

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

Approved by:
Susan Murphy
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.