



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

Crospon Ltd

Galway Business Park

Dangan

Co. Galway

Ireland

to the Product Family

**Esophageal Balloon Catheter and Inflator
(EndoFLIP® Functional Lumen Imaging Probe)**

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: 252.784

Original Approval: 09 January 2009

Last Amended on: 10 January 2012

Remains valid until: 31 July 2012

Signed:

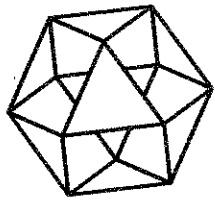
Approved by:
Kevin D. Mullaney
Chief Executive Officer - NSAI Inc.

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.



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Attachment to Certificate 252.784 dated 09 January 2009

This Certificate covers 17 model(s)

Model Reference	Detail
EF-100	EndoFLIP® System (PAL)
EF-400	EndoFLIP® System Cart
EF-500	EndoFLIP® Power Supply
LK-100	EndoFLIP® System Localisation Kit (UK./Ire)
LK-101	EndoFLIP® System Localisation Kit (EU)
LK-102	EndoFLIP® System Localisation Kit (Scandinavia)
LK-103	EndoFLIP® System Localisation Kit (US)
LK-104	EndoFLIP® System Localisation Kit (South America)
LK-105	EndoFLIP® System Localisation Kit (Australia)
LK-106	EndoFLIP® System Localisation Kit (Japan)
EF-325	Catheter – 25mm (Box of 5)
EF-335	Catheter – 35mm (Box of 5)
EF-350	Catheter – 50mm (Box of 5)
EF-325N	Catheter, Nasal – 25mm (Box of 5)
BF-325	Catheter, Gastric-Band
EF-620	Catheter, Gastric Sleeve
EF-900	EndoFLIP Gastric Tube