



APPROVAL OF CONFORMITY CERTIFICATE

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

Scholten Surgical Instruments, Inc.
170 Commerce Street, Suite 101
Lodi, California 95240, USA

has been assessed against the requirements of Annex II of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown below:

Novatome™ Endomyocardial Biopsy Forceps

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No: 4000745/B
Original Approval: December 16, 2008
Current Certificate: December 16, 2008
Certificate Expiry: December 15, 2011

LRQA Notified Body Number 0088



Issued by: Lloyd's Register Quality Assurance Limited