



## APPROVAL OF CONFORMITY CERTIFICATE

In accordance with the requirements of the Directive 93/42/EEC and  
Medical Devices Regulation 2002:618.

This is to certify that the Quality Management System of:

**Astra Tech AB**  
**Aminogatan 1, PO Box 14, SE 431 21**  
**Mölndal, Sweden**

has been assessed against the requirements of Annex II of the Directive 93/42/EEC,  
and the Medical Devices Regulation 2002:618 and conforms to the requirements  
for the products shown below:

### Products as listed on Certificate Schedule.

This certificate is valid only in association with the certificate schedule bearing the  
same number on which the products applicable to this approval are listed.

Approval is subject to the continued maintenance of the quality system in  
accordance with the requirements of LRQA approval 0945580/B and the  
requirements of the above mentioned Directive and Regulation.

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: LRQ 0945580/C

Original Approval: 8 May 1996

Current Certificate: 1 April 2008

Certificate Expiry: 31 March 2011

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited



## **APPROVAL OF CONFORMITY CERTIFICATE SCHEDULE**

**In accordance with the requirements of the Directive 93/42/EEC and  
Medical Devices Regulation 2002:618.**

**Astra Tech AB  
Aminogatan 1, PO Box 14, SE 431 21  
Mölndal, Sweden**

### **Annex II Products**

Dental Implant Surgical Components (Class IIa or Class IIb)  
Dental Implant Prosthetics and Laboratory Components (Class IIa)  
Dental Implant Instruments (Class IIa)  
Surgical Suction Systems (Class IIa)  
Varicose Vein Instruments (Class IIa)  
Haemorrhoid Ligation Instruments (Class IIa)  
Urotherapy Devices (Class IIa)  
Surgical Wound Drainage and Blood Reinfusion Systems (Class IIa or Class IIb)  
Bone Trap (Class IIa)  
Fluted Silicone Drain (Class IIa)  
Fatcher fat-reducing blood bag

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