



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:

**Kimal plc
Arundel Road, Uxbridge, Middlesex, UB8 2SA
United Kingdom**

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 on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations. In addition for Class III products approval is subject to the continued compliance with the EC Design Examination Certificate(s) as listed on the attached schedule.

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 0929603/B

Original Approval: 6 October 1995

Current Certificate: 17 June 2009

Certificate Expiry: 31 March 2012

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited



**APPROVAL OF CONFORMITY CERTIFICATE
CERTIFICATE LRQ 0929603/B SCHEDULE**

**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**

**Kimal plc
Arundel Road, Uxbridge, Middlesex, UB8 2SA
United Kingdom**

Class II Products

Guide Wires
Catheters, Cannulae and Accessory Devices
Fistula Needles and other Needles
Non-Direct Fluid Passage Devices and External Holding Devices
Sterile Blood and Solution Tubing/Lines
Systems and Procedure Packs

Class III Products

**EC Design Examination
Certificate**

Kimal Right Atrial Catheters	0088/0929603/00096
Kimal Long Term Access Catheters	0088/0929603/00247
Peel-Away Sheath Introducer	0088/0929603/00220
AngioFLEX™ GuideWires	0088/0929603/00085
Temporary Transvenous Cardiac Pacing Catheters	0088/0929603/00083
AngiofOw Cardiac Catheters	0088/0929603/00086

Schedule Issue: 3
Date of Schedule Issue: 17 June 2009
LRQA Notified Body Number 0088

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