



Lloyd's Register
LRQA

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

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: 1 April 2015

Certificate Expiry: 31 March 2018

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited



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EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM 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 IIa Products

AngioGATE® Paediatric HV Micro Introducer Kit
Guide Wires
Altius Guidewire & Dispensers
Catheters, Cannulae and Accessory Devices
Fistula Needles and other Needles
Non-Direct Fluid Passage Devices and External Holding Devices
KFlow short term access catheters – Temporary and 360° Temporary
Biocut Bone Biopsy Devices
Biocut Soft Tissue Biopsy Devices

Class IIb Products

Sterile Blood and Solution Tubing/Lines
Multipurpose Drainage Catheter

Systems & Procedure Packs

Cardiology/Pacing Universal
Radiology Universal
Cardiology/Angiography Universal





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Class III Products

K Flow Long Term Access Catheters
Peel-Away Sheath Introducer
AngioFLEX™ GuideWires
Temporary Transvenous Cardiac Pacing Catheters
Altius® Central Venous Catheter Sets
Peripherally Inserted Central Venous Catheters
K Flow Peripherally Inserted Central Venous Catheters

EC Design Examination Certificate

0088/0929603/00367
0088/0929603/00220
0088/0929603/00085
0088/0929603/00083
0088/0929603/00376
0088/0929603/00382
0088/0929603/00359

Schedule Issue: 01
Date of Schedule Issue: 1 April 2015
LRQA Notified Body Number 0088



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