



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: 12 April 2018

Certificate Expiry: 31 March 2021

LRQA Notified Body Number 0088



Issued by: Lloyd's Register Quality Assurance Limited



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
United Kingdom**

Class IIa Products

Fistula Needle
Kimal Vessel Dilator
Inflation Device
Introducer Needles
B Introducer Needles
AngioGATE Introducer Kits
Atrion Inflation Device / Angioflex Inflation Device
Manometre Lines
K Flow Epic Short Term
Angioflex Extension Lines
Stop Cocks
Manifolds
Contrast Media Lines
Bone Biopsy
Syringes
Soft Tissue Biopsy
Connectors
Accessories
Drainage Needles
Guidewires & Dispensers
Angel Catheter Accessory kit
Bloodlines
Midline Catheters
Surgical Instruments
Altius RT Acute Short term HD catheter kits
Guidewires

Cardiovascular procedure packs
Radiology procedure packs
Dialysis procedure packs
General surgery procedure packs
Community healthcare procedure packs





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Arundel Road,
Uxbridge, Middlesex
United Kingdom**

Class IIb Products

Peritoneal Dialysis Catheters & Kits

Class III Products

Peel-Away Sheath Introducer
AngioFLEX™ GuideWires
Temporary Transvenous Cardiac Pacing Catheters
Altius® Central Venous Catheter Sets
KFlow Long term access catheter
KflowEpic Dialysis Catheters & Kits for Long Term Use

EC Design Examination Certificate

0088/0929603/00220
0088/0929603/00085
0088/0929603/00083
0088/0929603/00376
0088/0929603/00367
0088/0929603/00393

Schedule Issue: 01

Date of Schedule Issue: 12 April 2018

LRQA Notified Body Number 0088



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