EC Declaration of Conformity to Council Directive 93/42/EEC

Manufacturer:	Kimal Plc Arundel Road Uxbridge Middlesex UB8 2SA United Kingdom

Devices	Connectors
Codes	See attached schedule
General Description	Catheters, Cannulae & Accessory Devices
EC Product Class	Class IIa - Rule 2
GMDN Code	32339 - Catheter connector, general-purpose

Declaration of Conformity

Kimal *declares that the Connectors listed on the attached Schedule of Products conform to the relevant provisions of the EC Council Directive 93/42/EEC on the approximation of the laws of the Member States relating to medical devices dated 14 June 1993 as amended by Council Directives 98/79/EC, 2000/70/EC, 2001/104/EC, 2007/47/EC and Regulation (EC) No. 1882/2003 and are in accordance with Annex II Conformity Assessment Procedure and EN ISO 13485 registered Quality Management System as implemented by Statutory Instrument 2002 No. 618, The Medical Devices Regulations 2002 Consumer Protection, as verified by LRQA. (* CE *0088).*

Kimal *confirms that no other application has been lodged with another Notified Body for the same product-related Quality Management System.*

Kimal *undertakes to develop, implement and maintain a formally-recognised Quality Management System to ensure continued adequacy and efficacy.*

Kimal *undertakes to develop, implement and maintain a documented post-production experience monitoring programme, along with notification of incidents notifiable under the European Medical Device Vigilance system guidelines.*

Kimal *confirms that no medicinal products/drugs, human blood derivatives, or ancillary substances are incorporated in any devices covered by the Product Schedule.*

Kimal *undertakes to inform the appointed Notified Body of any planned or unplanned substantial change to the Quality Management System.*

Kimal *undertakes to inform the appointed Notified Body of any planned or unplanned significant change to the Schedule of Products, including significant design change to devices.*

Authorisation

Designated Representative	James Bartlett Group Quality & Regulatory Affairs Manager	Date: 21/11/16
Signed for **Kimal Plc**		

EC Declaration of Conformity
Product Schedule for Connectors

Product Code	Product Description
K402	Connector
K406	Male/female connector set
K61/2	Male/male luerlock connector
K61/3	Male to male connector
K61/8	Connector Rotating
K61/9	Male Luer Lock Cap (X2)
K70/36	Anti – Siphon Valve
K407	Y-Site Accessory Set
K407/A	Y-Site Accessory Set
K407REVC	Y-Site Reversed 2m1F W Clamp
K41/8	Non-latex injection cap – male luer lock
K48/RB	Replacement luer connectors (pack of 2)
K408	Female/ Female Connector
KS429	Dialyser Bypass Connector
K68/88/7	Angioflow Y Connector With Sidearm