EU DECLARATION OF CONFORMITY

According to Article 11 of Council Directive 93/42/EEC

MANUFACTURER

Name:	Kimal PLC
SRN:	N/A
Address:	Arundel Road, Uxbridge, Middlesex, UB8 2SA, United Kingdom

AUTHORISED REPRESENTATIVE

Name:	Advena Ltd
Address:	Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013 Malt

PRODUCT RANGE

Name:	Altius RT Acute Haemodialysis Catheter Kits
Codes:	See attached schedule

ACCREDITATIONS – issued by Kiwa Turkey (NB 1984) under Council Directive 93/42/EEC

Certificate Type	Certificate No.
EC Full Quality Assurance System – Annex II	1984-MDD-20-695

DECLARATION

Kimal PLC hereby declares that the devices listed on the attached product schedule, fulfil the requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices as amended by Directive 2007/47/EC, and are subject to the conformity assessment as specified in Annex II, excluding Section 4.

The technical documentation has been drawn up in accordance with Section 3.2 of Annex II, and is available at the premises of Kimal PLC. This declaration is issued under the sole responsibility of Kimal PLC.

AUTHORISATION

Person Responsible for Regulatory Compliance on behalf of Kimal PLC:

X

Amanda Makemson
Group Quality & Regulatory Director

Date: 16 December 2020

LIST OF HARMONISED STANDARDS

The following table indicates the list of harmonised standards applied to this product range, for which documented evidence is included in the Technical File.

STANDARD NUMBER	TITLE
BS EN 556-1:2001	Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices
BS EN 1041:2008+A1:2013	Information supplied by the manufacturer with medical devices
BS EN 62366-1:2015	Medical devices Part 1: Application of usability engineering to medical devices
BS EN ISO 10555-1:2013+A1:2017	Intravascular catheters - Sterile and single-use catheters. Part 1: General requirements
BS EN ISO 10555-3:2013	Intravascular catheters — Sterile and single-use catheters Part 3: Central venous catheters
BS EN ISO 10993-1:October 2009	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
BS EN ISO 10993-3:2014	Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
BS EN ISO 10993-4:2017	Biological evaluation of medical devices. Part 4: Selection of tests for interactions with blood
BS EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
BS EN ISO 10993-6:2016	Biological evaluation of medical devices Part 6: Tests for local effects after implantation
BS EN ISO 10993-7:2008	Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals
BS EN ISO 10993-10:2013	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
BS EN ISO 10993-11:2018	Biological evaluation of medical devices – Tests for systemic toxicity
BS EN ISO 10993-12:2012	Biological evaluation of medical devices Part 12: Sample preparation and reference materials
BS EN ISO 10993-13:2010	Biological evaluation of medical devices Part 13: Identification and quantification of degradation products from polymeric medical devices
BS EN ISO 10993-16:2017	Biological evaluation of medical devices – Part 16: Toxicokinetic study design for degradation products and leachables
BS EN ISO 10993-17:2009	Biological evaluation of medical devices Part 17: Establishment of allowable limits for leachable substances

STANDARD NUMBER	TITLE
BS EN ISO 10993-18:2020	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process
BS EN ISO 11070:2014+A1:2018	Sterile single-use intravascular introducers, dilators and guidewires
BS EN ISO 11135:2014	Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices
BS EN ISO 11138-1:2017	Sterilization of health care products – Biological indicators Part 1: General requirements
BS EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices – Requirements for materials, sterile barrier systems and packaging systems
BS EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices – Validation requirements for forming, sealing and assembly processes
BS EN ISO 11737-1:2018	Sterilization of health care products – Microbiological methods Part 1: Determination of a population of microorganisms on products
BS EN ISO 11737-2:2020	Sterilization of medical devices – Microbiological methods Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
BS EN ISO 13485:2016	Medical devices-quality management system – requirements for regulatory purposes (second edition)
BS EN ISO 14644-1:2015	Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness by particle concentration
BS EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
BS EN ISO 15223-1:2016	Medical devices – Medical device symbols to be used with medical device labels. Labelling and information to be supplied. General requirements.
BS EN ISO 80369-7:2017	Small-bore connectors for liquids and gases in healthcare applications Part 7: Connectors for intravascular or hypodermic applications

PRODUCT SCHEDULE

PRODUCT IDENTIFICATION			
Product range name	Altius RT Haemodialysis Catheter Kits	**Classification**	Class IIa – Rule 7
Intended use	Sterile single use device indicated for use in attaining short term access for channelling and removal of substances during Haemodialysis treatment.		
GMDN code and term		**MDN code and term**	
60879 – Haemodialysis catheterization kit		1202 – Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	
MDS code(s) and term(s)	1005 – Devices in sterile condition		
MDT code(s) and term(s)	2002 – Devices manufactured using plastic processing 2008 – Devices manufactured in clean rooms and associated controlled environments 2011 – Devices which require packaging, including labelling		
CND code(s) and term(s)	N/A		

PRODUCT CODE	PRODUCT DESCRIPTION	UDI-DI
ART-ADL-1215-K	ALTIUS RT ACUTE 12FR 15CM DUAL LUMEN HAEMODIALYSIS CATHETER	05032932093930
ART-ADL-1217-K	ALTIUS RT ACUTE 12FR 17CM DUAL LUMEN HAEMODIALYSIS CATHETER	05032932092988
ART-ADL-1220-K	ALTIUS RT ACUTE 12FR 20CM DUAL LUMEN HAEMODIALYSIS CATHETER	05032932092384
ART-ADL-1225-K	ALTIUS RT ACUTE 12FR 25CM DUAL LUMEN HAEMODIALYSIS CATHETER	05032932093923
ART-ADL-1415-K	ALTIUS RT ACUTE 14FR 15CM DUAL LUMEN HAEMODIALYSIS CATHETER	05032932086710
ART-ADL-1417-K	ALTIUS RT ACUTE 14FR 17CM DUAL LUMEN HAEMODIALYSIS CATHETER	05032932092995

PRODUCT CODE	PRODUCT DESCRIPTION	UDI-DI
ART-ADL-1420-K	ALTIUS RT ACUTE 14FR 20CM DUAL LUMEN HAEMODIALYSIS CATHETER	05032932089957
ART-ADL-1425-K	ALTIUS RT ACUTE 14FR 25CM DUAL LUMEN HAEMODIALYSIS CATHETER	05032932092025