

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 Malta

PRODUCT RANGE

Name: Altius HP and High Flow Central Venous Catheter Sets
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
EC Design Examination – Annex II, Section 4	1984-MDD-20-718

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.

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:

 Recoverable Signature

X 

Amanda Makemson
Group Quality & Regulatory Director
Signed by: 57dd34df-1e09-4dc7-a910-d15573d3ee25

Date: 07 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 11737-2:2009	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.



PRODUCT SCHEDULE

PRODUCT IDENTIFICATION			
Product range name	Altius HP and High Flow Central Venous Catheter Sets	Classification	Class III – Rule 7 (1)
Intended use	Altius HP and High Flow Central Venous Catheter Sets are a combination of sterile, single use, surgically invasive devices intended for short-term use. Central venous catheters are indicated for use in attaining access to the central venous system, and are used for the purpose of: <ul style="list-style-type: none">• administration of vasoactive/inotropic drugs,• administration of incompatible medications,• administration of hypertonic solutions including total parental nutrition,• frequent blood sampling,• blood transfusion,• measurement of central venous pressure (CVP),• power injection of contrast media – Altius HP pressure resistant catheters only.		
GMDN code and term		MDN code and term	
61594 – Central venous catheterization kit, short-term		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 2006 – Devices manufactured using chemical 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		



SECTION 15 DECLARATION OF CONFORMITY

REVISION: 0015

PRODUCT CODE	PRODUCT DESCRIPTION	UDI-DI
K2CS111501P	ALTIUS HP 1 LUMEN CVC SET 5FR (16GA) 11CM	05032932035961
K2CS111701P	ALTIUS HP 1 LUMEN CVC SET 7FR (14GA) 11CM	05032932035978
K2CS111702P	ALTIUS HP 2 LUMEN CVC SET 7FR 11CM	05032932035985
K2CS111703P	ALTIUS HP 3 LUMEN CVC SET 7FR 11CM	05032932036005
K2CS111802P	ALTIUS HP 2 LUMEN CVC SET 8FR 11CM	05032932036012
K2CS111803P	ALTIUS HP 3 LUMEN CVC SET 8FR 11CM	05032932036029
K2CS111856P	ALTIUS HP 6 LUMEN CVC SET 8.5FR 11CM	05032932050476
K2CS111904P	ALTIUS HP 4 LUMEN CVC SET 9FR 11CM	05032932050308
K2CS111905P	ALTIUS HP 5 LUMEN CVC SET 9FR 11CM	05032932050315
K2CS115501P	ALTIUS HP 1 LUMEN CVC SET 5FR 16GA 15CM	05032932035176
K2CS115701P	ALTIUS HP 1 LUMEN CVC SET 7FR 14GA 15CM	05032932035206
K2CS115702P	ALTIUS HP 2 LUMEN CVC SET 7FR 15CM	05032932036111
K2CS115702PECG	ALTIUS HP 2 LUMEN CVC SET 7FR 15CM ECG	05032932050377
K2CS115703P	ALTIUS HP 3 LUMEN CVC SET 7FR 15CM	05032932036135
K2CS115703PECG	ALTIUS HP 3 LUMEN CVC SET 7FR 15CM ECG	05032932050391
K2CS115802P	ALTIUS HP 2 LUMEN CVC SET 8FR 15CM	05032932035237
K2CS115802PECG	ALTIUS HP 2 LUMEN CVC SET 8FR 15CM ECG	05032932050407
K2CS115803P	ALTIUS HP 3 LUMEN CVC SET 8FR 15CM	05032932035244
K2CS115803PECG	ALTIUS HP 3 LUMEN CVC SET 8FR 15CM ECG	05032932050414
K2CS115856P	ALTIUS HP 6 LUMEN CVC SET 8.5FR 15CM	05032932050476



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PRODUCT CODE	PRODUCT DESCRIPTION	UDI-DI
K2CS115904P	ALTIUS HP 4 LUMEN CVC SET 9FR 15CM	05032932036197
K2CS115904PECG	ALTIUS HP 4 LUMEN CVC SET 9FR 15CM ECG	05032932050490
K2CS115905P	ALTIUS HP 5 LUMEN CVC SET 9FR 15CM	05032932050506
K2CS115905PECG	ALTIUS HP 5 LUMEN CVC SET 9FR 15CM ECG	05032932050513
K2CS120501P	ALTIUS HP 1 LUMEN CVC SET 5FR 16GA 20CM	05032932035275
K2CS120701P	ALTIUS HP 1 LUMEN CVC SET 7FR 14GA 20CM	05032932035299
K2CS120702P	ALTIUS HP 2 LUMEN CVC SET 7FR 20CM	05032932036234
K2CS120702PECG	ALTIUS HP 2 LUMEN CVC SET 7FR 20CM ECG	05032932050551
K2CS120703P	ALTIUS HP 3 LUMEN CVC SET 7FR 20CM	05032932036258
K2CS120703PECG	ALTIUS HP 3 LUMEN CVC SET 7FR 20CM ECG	05032932050568
K2CS120802P	ALTIUS HP 2 LUMEN CVC SET 8FR 20CM	05032932035336
K2CS120802PECG	ALTIUS HP 2 LUMEN CVC SET 8FR 20CM ECG	05032932050575
K2CS120803P	ALTIUS HP 3 LUMEN CVC SET 8FR 20CM	05032932036265
K2CS120803PECG	ALTIUS HP 3 LUMEN CVC SET 8FR 20CM ECG	05032932050582
K2CS120856P	ALTIUS HP 6 LUMEN CVC SET 8.5FR 20CM	05032932050629
K2CS120904P	ALTIUS HP 4 LUMEN CVC SET 9FR 20CM	05032932036326
K2CS120904PECG	ALTIUS HP 4 LUMEN CVC SET 9FR 20CM ECG	05032932050643
K2CS120905P	ALTIUS HP 5 LUMEN CVC SET 9FR 20CM	05032932035367
K2CS120905PECG	ALTIUS HP 5 LUMEN CVC SET 9FR 20CM ECG	05032932050667
K2CS130501P	ALTIUS HP 1 LUMEN CVC SET 5FR (16GA) 30CM	05032932050728



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K2CS130701P	ALTIUS HP 1 LUMEN CVC SET 7FR (14GA) 30CM	05032932050735
K2CS130702P	ALTIUS HP 2 LUMEN CVC SET 7FR 30CM	05032932050742
K2CS130702PECG	ALTIUS HP 2 LUMEN CVC SET 7FR 30CM ECG	05032932050759
K2CS130703P	ALTIUS HP 3 LUMEN CVC SET 7FR 30CM	05032932050766
K2CS130703PECG	ALTIUS HP 3 LUMEN CVC SET 7FR 30CM ECG	05032932050773
K2CS130802P	ALTIUS HP 2 LUMEN CVC SET 8FR 30CM	05032932050780
K2CS130802PECG	ALTIUS HP 2 LUMEN CVC SET 8FR 30CM ECG	05032932050797
K2CS130803P	ALTIUS HP 3 LUMEN CVC SET 8FR 30CM	05032932050803
K2CS130803PECG	ALTIUS HP 3 LUMEN CVC SET 8FR 30CM ECG	05032932050810
K2CS130856P	ALTIUS HP 6 LUMEN CVC SET 8.5FR 30CM	05032932050834
K2CS130904P	ALTIUS HP 4 LUMEN CVC SET 9FR 30CM	05032932050841
K2CS130904PECG	ALTIUS HP 4 LUMEN CVC SET 9FR 30CM ECG	05032932050858
K2CS130905P	ALTIUS HP 5 LUMEN CVC SET 9FR 30CM	05032932050865
K2CS130905PECG	ALTIUS HP 5 LUMEN CVC SET 9FR 30CM ECG	05032932050872
K2CS111852HF	ALTIUS HIGH FLOW 2 LUMEN 8.5FR 11CM	05032932050254
K2CS115852HF	ALTIUS HIGH FLOW 2 LUMEN CVC SET 8.5FR 15CM	05032932050438
K2CS120852HF	ALTIUS HIGH FLOW 2 LUMEN CVC SET 8.5FR 20CM	05032932050605
K2CS125852HF	ALTIUS HIGH FLOW 2 LUMEN CVC SET 8.5FR 25CM	05032932050704
K2CS111853HF	ALTIUS HIGH FLOW 3 LUMEN CVC SET 8.5FR 11CM	05032932050278
K2CS115853HF	ALTIUS HIGH FLOW 3 LUMEN CVC SET 8.5FR 15CM	05032932050445



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K2CS120853HF	ALTIUS HIGH FLOW 3 LUMEN CVC SET 8.5FR 20CM	05032932050612
K2CS125853HF	ALTIUS HIGH FLOW 3 LUMEN CVC SET 8.5FR 25CM	05032932050711
K2CS111124HF	ALTIUS HIGH FLOW 4 LUMEN CVC SET 12FR 11CM	05032932050209
K2CS115124HF	ALTIUS HIGH FLOW 4 LUMEN CVC SET 12FR 15CM	05032932050339
K2CS120124HF	ALTIUS HIGH FLOW 4 LUMEN CVC SET 12FR 20CM	05032932050520
K2CS125124HF	ALTIUS HIGH FLOW 4 LUMEN CVC SET 12FR 25CM	05032932050674
K2CS1111255HF	ALTIUS HIGH FLOW 5 LUMEN CVC SET 12.5FR 11CM	To be decided
K2CS1151255HF	ALTIUS HIGH FLOW 5 LUMEN CVC SET 12.5FR 15CM	To be decided
K2CS1201255HF	ALTIUS HIGH FLOW 5 LUMEN CVC SET 12.5FR 20CM	To be decided
K2CS1251255HF	ALTIUS HIGH FLOW 5 LUMEN CVC SET 12.5FR 25CM	To be decided
K2CS111852PHF	ALTIUS HIGH FLOW HP 2 LUMEN CVC SET 8.5FR 11CM	05032932050261
K2CS115852PHF	ALTIUS HIGH FLOW HP 2 LUMEN CVC SET 8.5FR 15CM	To be decided
K2CS120852PHF	ALTIUS HIGH FLOW HP 2 LUMEN CVC SET 8.5FR 20CM	To be decided
K2CS125852PHF	ALTIUS HIGH FLOW HP 2 LUMEN CVC SET 8.5FR 25CM	To be decided
K2CS111853PHF	ALTIUS HIGH FLOW HP 3 LUMEN CVC SET 8.5FR 11CM	05032932050285
K2CS115853PHF	ALTIUS HIGH FLOW HP 3 LUMEN CVC SET 8.5FR 15CM	To be decided
K2CS120853PHF	ALTIUS HIGH FLOW HP 3 LUMEN CVC SET 8.5FR 20CM	To be decided
K2CS125853PHF	ALTIUS HIGH FLOW HP 3 LUMEN CVC SET 8.5FR 25CM	To be decided
K2CS111124PHF	ALTIUS HIGH FLOW HP 4 LUMEN CVC SET 12FR 11CM	05032932050216
K2CS115124PHF	ALTIUS HIGH FLOW HP 4 LUMEN CVC SET 12FR 15CM	To be decided



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K2CS120124PHF	ALTIUS HIGH FLOW HP 4 LUMEN CVC SET 12FR 20CM	To be decided
K2CS125124PHF	ALTIUS HIGH FLOW HP 4 LUMEN CVC SET 12FR 25CM	To be decided
K2CS1111255PHF	ALTIUS HIGH FLOW HP 5 LUMEN CVC SET 12.5FR 11CM	05032932050223
K2CS1151255PHF	ALTIUS HIGH FLOW HP 5 LUMEN CVC SET 12.5FR 15CM	05032932050346
K2CS1201255PHF	ALTIUS HIGH FLOW HP 5 LUMEN CVC SET 12.5FR 20CM	05032932050537
K2CS1251255PHF	ALTIUS HIGH FLOW HP 5 LUMEN CVC SET 12.5FR 25CM	05032932050681
K2CS1111256PHF	ALTIUS HIGH FLOW HP 6 LUMEN CVC SET 12.5FR 11CM	05032932050230
K2CS1151256PHF	ALTIUS HIGH FLOW HP 6 LUMEN CVC SET 12.5FR 15CM	05032932050353
K2CS1201256PHF	ALTIUS HIGH FLOW HP 6 LUMEN CVC SET 12.5FR 20CM	05032932050544
K2CS1251256PHF	ALTIUS HIGH FLOW HP 6 LUMEN CVC SET 12.5FR 25CM	05032932050698

