

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: KFlow Epic Short Term Haemodialysis Catheters & Kits
Codes: See attached schedule

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

EC Full Quality Assurance System – Annex II

Certificate No.

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:

 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
ASTM D 4169-16	Performance Testing of Shipping Containers and Systems
ASTM F 1140 13	Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
ASTM F 1929 15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
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 – Application of usability engineering to medical devices
BS EN ISO 10555-1:2013+A1:2017	Intravascular catheters. Sterile and single-use catheters. General requirements
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 sterilisation 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 : Part 11 – 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 identification and quantification of degradation products from polymeric medical devices
BS EN ISO 10993-16 2017	Biological evaluation of medical devices. Toxicokinetic study design for degradation products and leachables



STANDARD NUMBER	TITLE
BS EN ISO 10993-17:2009	Biological evaluation of medical devices. Establishment of allowable limits for leachable substances
BS EN ISO 10993-18 2009	Biological evaluation of medical devices Part 18: Chemical characterization of materials (ISO 10993-18:2005)
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. Connectors for intravascular or hypodermic applications



PRODUCT SCHEDULE

PRODUCT IDENTIFICATION			
Product range name	KFlow Epic Short Term Haemodialysis Catheters & Kits – Single Lumen	Classification	Class IIa – Rule 7
Intended use	Sterile single use device indicated for use in attaining short term (30 days) access for Haemodialysis or aphaeresis.		
GMDN code and term		MDN code and term	
61630 - Haemodialysis/central venous 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)	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 ¹
KFE-TSL-0710-K	SHORT TERM SINGLE LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 7 FR LENGTH 10 CM	05032932080732
KFE-TSL-0712-K	SHORT TERM SINGLE LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 7 FR LENGTH 12 CM	05032932080763
KFE-TSL-0810-K	SHORT TERM SINGLE LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 8 FR LENGTH 10 CM	05032932080794

¹ If UDI-DI is marked as TBA, the product is not currently manufactured. The UDI will be updated and printed on all labels as per Kimal's internal procedures during manufacturing.



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PRODUCT CODE	PRODUCT DESCRIPTION	UDI-DI ¹
KFE-TSL-0812-K	SHORT TERM SINGLE LUMEN STRAIGHT FEMORAL HAEMODIALYSIS CATHETER KIT SIZE 8 FR LENGTH 12 CM	05032932080824
KFE-TSL-0815-K	SHORT TERM SINGLE LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 8 FR LENGTH 15 CM	05032932045984
KFE-TSL-0820-K	SHORT TERM SINGLE LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 8 FR LENGTH 20 CM	05032932046004
KFE-TSL-0710-JK	SHORT TERM SINGLE LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 7 FR LENGTH 10 CM	05032932082392
KFE-TSL-0712-JK	SHORT TERM SINGLE LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 7 FR LENGTH 12 CM	05032932080756
KFE-TSL-0810-JK	SHORT TERM SINGLE LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 8 FR LENGTH 10 CM	05032932080787
KFE-TSL-0812-JK	SHORT TERM SINGLE LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 8 FR LENGTH 12 CM	05032932080817
KFE-TSL-0815-JK	SHORT TERM SINGLE LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 8 FR LENGTH 15 CM	05032932045977
KFE-TSL-0820-JK	SHORT TERM SINGLE LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 8 FR LENGTH 20 CM	05032932080848
KFE-TSL-0710-PCK	SHORT TERM SINGLE LUMEN PRECURVED HAEMODIALYSIS CATHETER KIT SIZE 7 FR LENGTH 10 CM	05032932080749
KFE-TSL-0712-PCK	SHORT TERM SINGLE LUMEN PRECURVED HAEMODIALYSIS CATHETER KIT SIZE 7 FR LENGTH 12 CM	05032932080770
KFE-TSL-0810-PCK	SHORT TERM SINGLE LUMEN PRECURVED HAEMODIALYSIS CATHETER KIT SIZE 8 FR LENGTH 10 CM	05032932080800



PRODUCT CODE	PRODUCT DESCRIPTION	UDI-DI ¹
KFE-TSL-0812-PCK	SHORT TERM SINGLE LUMEN PRECURVED HAEMODIALYSIS CATHETER KIT SIZE 8 FR LENGTH 12 CM	05032932080831
KFE-TSL-0815-PCK	SHORT TERM SINGLE LUMEN PRECURVED HAEMODIALYSIS CATHETER KIT SIZE 8 FR LENGTH 15 CM	05032932045991
KFE-TSL-0820-PCK	SHORT TERM SINGLE LUMEN PRECURVED HAEMODIALYSIS CATHETER KIT SIZE 8 FR LENGTH 20 CM	05032932080855



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PRODUCT IDENTIFICATION			
Product range name	KFlow Epic Short Term Haemodialysis Catheters & Kits – Dual Lumen	Classification	Class IIa – Rule 7
Intended use	Sterile single use device indicated for use in attaining short term (30 days) access for Haemodialysis or aphaeresis.		
GMDN code and term		MDN code and term	
61630 - Haemodialysis/central venous 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)	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 ²
KFE-TDL-0608-KP	SHORT TERM DUAL LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 6 FR LENGTH 8 CM PAEDIATRIC	05032932043737
KFE-TDL-0710-KP	SHORT TERM DUAL LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 7 FR LENGTH 10 CM PAEDIATRIC	05032932043751
KFE-TDL-0713-KP	SHORT TERM DUAL LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 7 FR LENGTH 13 CM PAEDIATRIC	05032932043768
KFE-TDL-0810-KP	SHORT TERM DUAL LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 8 FR LENGTH 10 CM PAEDIATRIC	05032932043782

² If UDI-DI is marked as TBA, the product is not currently manufactured. The UDI will be updated and printed on all labels as per Kimal's internal procedures during manufacturing.



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PRODUCT CODE	PRODUCT DESCRIPTION	UDI-DI ²
KFE-TDL-0813-KP	SHORT TERM DUAL LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 8 FR LENGTH 13 CM PAEDIATRIC	05032932043799
KFE-TDL-0910-KP	SHORT TERM DUAL LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 9 FR LENGTH 10 CM PAEDIATRIC	05032932043812
KFE-TDL-0913-KP	SHORT TERM DUAL LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 9 FR LENGTH 13 CM PAEDIATRIC	05032932043829
KFE-TDL-1012-K	SHORT TERM DUAL LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 10 FR LENGTH 12 CM	05032932043843
KFE-TDL-1015-K	SHORT TERM DUAL LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 10 FR LENGTH 15 CM	05032932043850
KFE-TDL-1212-K	SHORT TERM DUAL LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 11.5-12 FR LENGTH 12 CM	05032932090397
KFE-TDL-1215-K	SHORT TERM DUAL LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 11.5-12 FR LENGTH 15 CM	05032932008316
KFE-TDL-1217-K	SHORT TERM DUAL LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 11.5-12 FR LENGTH 17 CM	05032932080602
KFE-TDL-1220-K	SHORT TERM DUAL LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 11.5-12 FR LENGTH 20 CM	05032932008323
KFE-TDL-1224-K	SHORT TERM DUAL LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 12 FR LENGTH 24 CM	05032932095965
KFE-TDL-1415-K	SHORT TERM DUAL LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 14 FR LENGTH 15 CM	05032932008347
KFE-TDL-1417-K	SHORT TERM DUAL LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 14 FR LENGTH 17 CM	05032932080671



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KFE-TDL-1420-K	SHORT TERM DUAL LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 14 FR LENGTH 20 CM	05032932008361
KFE-TDL-1424-K	SHORT TERM DUAL LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 14 FR LENGTH 24 CM	05032932080718
KFE-TDL-0710-JKP	SHORT TERM DUAL LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 7 FR LENGTH 10 CM PAEDIATRIC	05032932043744
KFE-TDL-0713-JKP	SHORT TERM DUAL LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 7 FR LENGTH 13 CM PAEDIATRIC	05032932080503
KFE-TDL-0810-JKP	SHORT TERM DUAL LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 8 FR LENGTH 10 CM PAEDIATRIC	05032932043775
KFE-TDL-0813-JKP	SHORT TERM DUAL LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 8 FR LENGTH 13 CM PAEDIATRIC	05032932080510
KFE-TDL-0910-JKP	SHORT TERM DUAL LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 9 FR LENGTH 10 CM PAEDIATRIC	05032932043805
KFE-TDL-0913-JKP	SHORT TERM DUAL LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 9 FR LENGTH 13 CM PAEDIATRIC	05032932080527
KFE-TDL-1012-JK	SHORT TERM DUAL LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 10 FR LENGTH 12 CM	05032932043836
KFE-TDL-1015-JK	SHORT TERM DUAL LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 10 FR LENGTH 15 CM	05032932080534
KFE-TDL-1212-JK	SHORT TERM DUAL LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 11.5-12 FR LENGTH 12 CM	05032932080541
KFE-TDL-1215-JK	SHORT TERM DUAL LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 11.5-12 FR LENGTH 15 CM	05032932080572



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PRODUCT CODE	PRODUCT DESCRIPTION	UDI-DI ²
KFE-TDL-1217-JK	SHORT TERM DUAL LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 11.5-12 FR LENGTH 17 CM	05032932088578
KFE-TDL-1220-JK	SHORT TERM DUAL LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 11.5-12 FR LENGTH 20 CM	05032932080626
KFE-TDL-1224-JK	SHORT TERM DUAL LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 12 FR LENGTH 24 CM	05032932080640
KFE-TDL-1415-JK	SHORT TERM DUAL LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 14 FR LENGTH 15 CM	05032932008330
KFE-TDL-1417-JK	SHORT TERM DUAL LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 14 FR LENGTH 17 CM	05032932080664
KFE-TDL-1420-JK	SHORT TERM DUAL LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 14 FR LENGTH 20 CM	05032932008354
KFE-TDL-1424-JK	SHORT TERM DUAL LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 14 FR LENGTH 24 CM	05032932080701
KFE-TDL-1212-PCK	SHORT TERM DUAL LUMEN PRECURVED HAEMODIALYSIS CATHETER KIT SIZE 11.5-12 FR LENGTH 12 CM	05032932080565
KFE-TDL-1215-PCK	SHORT TERM DUAL LUMEN PRECURVED HAEMODIALYSIS CATHETER KIT SIZE 11.5-12 FR LENGTH 15 CM	05032932088561
KFE-TDL-1217-PCK	SHORT TERM DUAL LUMEN PRECURVED HAEMODIALYSIS CATHETER KIT SIZE 11.5-12 FR LENGTH 17 CM	05032932080619
KFE-TDL-1220-PCK	SHORT TERM DUAL LUMEN PRECURVED HAEMODIALYSIS CATHETER KIT SIZE 11.5-12 FR LENGTH 20 CM	05032932080633
KFE-TDL-1224-PCK	SHORT TERM DUAL LUMEN PRE CURVED HAEMODIALYSIS CATHETER KIT SIZE 12 FR LENGTH 24 CM	05032932080657



PRODUCT CODE	PRODUCT DESCRIPTION	UDI-DI ²
KFE-TDL-1415-PCK	SHORT TERM DUAL LUMEN PRECURVED HAEMODIALYSIS CATHETER KIT SIZE 14 FR LENGTH 15 CM	05032932082408
KFE-TDL-1417-PCK	SHORT TERM DUAL LUMEN PRECURVED HAEMODIALYSIS CATHETER KIT SIZE 14 FR LENGTH 17 CM	05032932080688
KFE-TDL-1420-PCK	SHORT TERM DUAL LUMEN PRECURVED HAEMODIALYSIS CATHETER KIT SIZE 14 FR LENGTH 20 CM	05032932080695
KFE-TDL-1424-PCK	SHORT TERM DUAL LUMEN PRECURVED HAEMODIALYSIS CATHETER KIT SIZE 14 FR LENGTH 24 CM	05032932080725



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PRODUCT IDENTIFICATION			
Product range name	KFlow Epic Short Term Haemodialysis Catheters & Kits – Triple Lumen	Classification	Class IIa – Rule 7
Intended use	Sterile single use device indicated for use in attaining short term (30 days) access for Haemodialysis or aphaeresis.		
GMDN code and term		MDN code and term	
61630 - Haemodialysis/central venous 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)	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 ³
KFE-TTL-1315-K	SHORT TERM TRIPLE LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 13 FR LENGTH 15 CM	05032932009986
KFE-TTL-1317-K	SHORT TERM TRIPLE LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 13 FR LENGTH 17 CM	05032932088639
KFE-TTL-1320-K	SHORT TERM TRIPLE LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 13 FR LENGTH 20 CM	05032932043867
KFE-TTL-1415-K	SHORT TERM TRIPLE LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 14 FR LENGTH 15 CM	05032932088547

³ If UDI-DI is marked as TBA, the product is not currently manufactured. The UDI will be updated and printed on all labels as per Kimal's internal procedures during manufacturing.



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PRODUCT CODE	PRODUCT DESCRIPTION	UDI-DI ³
KFE-TTL-1417-K	SHORT TERM TRIPLE LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 14 FR LENGTH 17 CM	05032932080954
KFE-TTL-1420-K	SHORT TERM TRIPLE LUMEN STRAIGHT HAEMODIALYSIS CATHETER KIT SIZE 14 FR LENGTH 15 CM	05032932089988
KFE-TTL-1315-JK	SHORT TERM TRIPLE LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 13 FR LENGTH 15 CM	05032932088585
KFE-TTL-1317-JK	SHORT TERM TRIPLE LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 13 FR LENGTH 17 CM	05032932088608
KFE-TTL-1320-JK	SHORT TERM TRIPLE LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 13 FR LENGTH 20 CM	05032932080329
KFE-TTL-1324-JK	SHORT TERM TRIPLE LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 13 FR LENGTH 24 CM	05032932080909
KFE-TTL-1415-JK	SHORT TERM TRIPLE LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 14 FR LENGTH 15 CM	05032932095606
KFE-TTL-1417-JK	SHORT TERM TRIPLE LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 14 FR LENGTH 17 CM	05032932080947
KFE-TTL-1420-JK	SHORT TERM TRIPLE LUMEN CURVED EXT HAEMODIALYSIS CATHETER KIT SIZE 14 FR LENGTH 20 CM	05032932080336
KFE-TTL-1315-PCK	SHORT TERM TRIPLE LUMEN PRE CURVED HAEMODIALYSIS CATHETER KIT SIZE 13 FR LENGTH 15 CM	05032932008378
KFE-TTL-1317-PCK	SHORT TERM TRIPLE LUMEN PRE CURVED HAEMODIALYSIS CATHETER KIT SIZE 13 FR LENGTH 17 CM	05032932080893
KFE-TTL-1320-PCK	SHORT TERM TRIPLE LUMEN PRE CURVED HAEMODIALYSIS CATHETER KIT SIZE 13 FR LENGTH 20 CM	05032932008385



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PRODUCT CODE	PRODUCT DESCRIPTION	UDI-DI ³
KFE-TTL-1415-PCK	SHORT TERM TRIPLE LUMEN PRE CURVED HAEMODIALYSIS CATHETER KIT SIZE 14 FR LENGTH 15 CM	05032932088622
KFE-TTL-1417-PCK	SHORT TERM TRIPLE LUMEN PRE CURVED HAEMODIALYSIS CATHETER KIT SIZE 14 FR LENGTH 17 CM	05032932080961
KFE-TTL-1420-PCK	SHORT TERM TRIPLE LUMEN PRE CURVED HAEMODIALYSIS CATHETER KIT SIZE 14 FR LENGTH 20 CM	05032932080985



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PRODUCT IDENTIFICATION			
Product range name	KFlow Epic Short Term Haemodialysis Catheters & Kits – Solo	Classification	Class IIa – Rule 7
Intended use	Sterile single use device indicated for use in attaining short term (30 days) access for Haemodialysis or aphaeresis.		
GMDN code and term		MDN code and term	
61630 - Haemodialysis/central venous 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)	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
KFE-SOLO-12	SHORT TERM 12FR X 25CM DUAL LUMEN CATHETER KIT	05032932043720
KFE-SOLO-14	SHORT TERM 14FR X 25CM DUAL LUMEN CATHETER KIT	05032932008309

