CERTIFICATE

# EC Certificate

## Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

**Certificate Number: 1984-MDD-20-695**

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

**Organization:**

## KIMAL Plc

Arundel Road, Uxbridge, Middlesex, UB8 2SA United Kingdom

**Products:** Sterile Fluid Management Devices, Sterile Textiles and Drapes, Procedure Packs, KFlow Peritoneal Dialysis Catheters & Kits, AngioGATE Introducer Kits, Catheters Insertion Components, Introducer Needles, Kimal Vessel Dilator, Altius RT Acute Short Term Haemodialysis Catheter Kits, K Flow Epic Short Term Haemodialysis Catheter & Kits, Midline Catheters Kits, Extracorporeal Circuits, Connectors and Valves For Fluid Management, Manometer Lines, Drainage Sets, Surgical Instruments, Altius Central Venous Catheter (CVC) Sets, K Flow Epic Long-Term Haemodialysis Catheters & Kits, Peripherally Inserted Central Catheters (PICCs), AngioFLEX Guidewires

The products defined at the enclosure which is the part of this certificate and contains four (4) pages. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Design Examination according to Medical Devices Directive 93/42/EEC Annex-II Section 4 certificate is also mandatory for class III devices covered by this certificate.

| | |
|---|---|
| **Report Number:** | M.5872.01 |
| **Date of first issue:** | 05 September 2020 |
| **Date of last issue:** | 25 February 2021 |
| **Revision Number:** | 03 |
| **Expiry Date:** | 27 May 2024 |

Muhteşem Gökhan Yücel
Head of Notified Body

25 February 2021, Istanbul, Turkey

**Kiwa Belgelendirme Hizmetleri A.Ş.**
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Web: www.kiwa.com.tr , e-mail: posta@kiwa.com

CERTIFICATE

**Enclosure of the EC Certificate:** 

**Full Quality Assurance System according to**
**Medical Devices Directive 93/42/EEC Annex-II.3**
**Certificate Number: 1984-MDD-20-695, Revision Number: 03**

Concerned medical devices;

**Product:** Sterile Fluid Management Devices (KSP-213)

| |
|---|
| (KSP-213A) Sterile Accessory Devices&Mini Procedure Sets (Dialysis) |
| (KSP-213B) Sterile External Drainage Sets and Holding Devices |

**Product:** Sterile Textiles and Drapes (KSP-216)

**Product:** Procedure Packs (KSP-215)

| |
|---|
| (KSP-215A) Cardiovascular Procedure Packs |
| (KSP-215D) Radiology Procedure Packs |
| (KSP-215C) Dialysis Procedure Packs |
| (KSP-215B) General Surgery Procedure Packs |

**Product:** KFlow Peritoneal Dialysis Catheters & Kits (KSP-024)

**Product:** AngioGATE Introducer Kits (KSP-098)

**Product:** Catheters Insertion Components (KSP-194)

| |
|---|
| (KSP-194A) Altius Guidewires & Dispensers |
| (KSP-194B) Kimal Guidewires & Dispensers |

**Product:** Introducer Needles (KSP-071)

**Product:** Kimal Vessel Dilator (KSP-049)

**Product:** Altius RT Acute Short-Term HD Catheter Kits (KSP-203)

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Concerned medical devices;

**Product:** KFlow Epic Short-Term Haemodialysis Catheter & Kits (KSP-132A)

**Product:** Midline Catheters Kits (KSP-200)

**Product:** Extracorporeal Circuits, Connectors and Valves for Fluid Management (KSP-212)

| |
|---|
| (KSP-212A) Angioflex Extension Lines |
| (KSP-212E) Connectors |
| (KSP-212D) Contrast Media Lines |
| (KSP-212F) KFE Connectors and Repair Valves |
| (KSP-212C) Manifolds and Manifold Sets |
| (KSP-212B) Stopcocks |
| (KSP-212H) Accessories |
| (KSP-212G) Syringes |

**Product:** Manometer Lines (KSP-125)

**Product:** Procedure Packs (KSP-107)

| |
|---|
| (KSP-107E) Dialysis Procedure Packs |
| (KSP-107D) General Surgery Procedure Packs |
| (KSP-107C) Cardiovascular Procedure Packs |
| (KSP-107B) Radiology Procedure Packs |

**Product:** Drainage Sets (KSP-189)

**Product:** Surgical Instruments (KSP-201)

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Concerned medical devices;

**Product:** Altius Central Venous Catheter (CVC) Sets (KSP-155)

| |
|---|
| (KSP-155A) Altius Classic Central Venous Catheter Sets |
| (KSP-155B) Altius 2nd generation Central Venous Catheter Sets |
| (KSP-155C) Altius HP and High Flow Central Venous Catheter Sets |
| (KSP-155D) Altius ProActiv+ Central Venous Catheter Sets |

**Product:** K Flow Epic Long-Term Haemodialysis Catheters & Kits (KSP-132B)

| |
|---|
| KFlow Epic Long-Term Haemodialysis Catheter Kits-Dual Lumen |
| KFlow Epic Long-Term Haemodialysis Catheter Kits-Dual Lumen With Side Holes |
| KFlow Epic Long-Term Haemodialysis Catheter Kits-Split Dual Lumen |
| KFlow Epic Long-Term Haemodialysis Catheter Kits-Split Dual Lumen With Side Holes |
| KFlow Epic Long-Term Haemodialysis Catheter Kits-Twin Cath |
| KFlow Epic Long-Term Haemodialysis Catheter Kits-Twin Cath With Side Holes |
| KFlow Epic Long-Term Haemodialysis Catheter Kits-Retro |
| KFlow Epic Long-Term Haemodialysis Catheter Kits-Retro With Side Holes |
| KFlow Epic Long-Term Haemodialysis Catheter Kits-Retro Split |
| KFlow Epic Long-Term Haemodialysis Catheter Kits-Retro Split With Side Holes |

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Concerned medical devices;

**Product:** Peripherally Inserted Central Catheters (PICCs) (KSP-198)

| |
|---|
| A.KIMAL PICC - (Pressure)<br>1. I.Over Dilator<br>2. II. Over Needle<br>3. III. KIMAL PICC - (Catheter Only) |
| B. KIMAL PICC - (Catheter Over Dilator Rawlinson Set) |
| C. KIMAL PICC - (Catheter Over Dilator Brazil Set) |
| D. KIMAL PICC - (Non-Pressure - Reverse Taper)<br>I. Over Dilator<br>II. Over Needle |

**Product:** AngioFLEX guidewires(KSP-217)

| |
|---|
| AngioFLEX uncoated stainless steel guidewires |
| AngioFLEX Teflon coated guidewires |
| AngioFLEX Hydrophilic coated guidewires |

| **List of Critical Suppliers:** | |
|---|---|
| **Location** | **Activity** |
| Kimal Medical Technologies<br><br>Plot No. 16, Block E, Nasr City Free Zone, Cairo, Egypt. | Manufacturing, ethylene oxide sterilisation and logistics for KFlow Epic Short-Term Haemodialysis Catheters & Kits, Altius RT Haemodialysis Catheters Kits, Midlines Catheters Kits, Altius Central Venous Catheter (CVC) Sets, KFlow Epic Long-Term Haemodialysis Catheters & Kits, Peripherally Inserted Central Catheters (PICCs), Guidewires, connectors, valves and small packs. |

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

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