BTC Medical Europe S.r.l.
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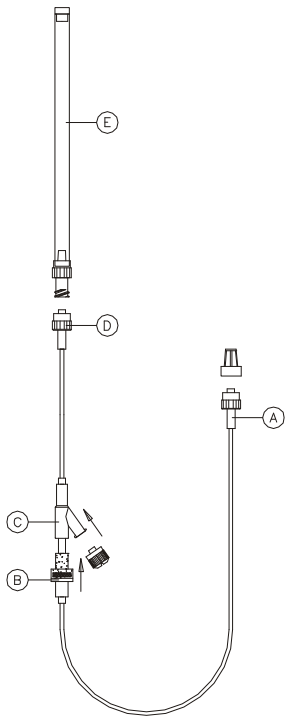
TECHNICAL SHEET
PATIENTS KIT IRIDE / WIS
CODE: 24A1D10003



CE 0051

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1.1 Intended use:

Kit for the administration of solutions or radiopharmaceuticals to the patient. Maximum Operating Pressure 3 bar = 40 psi
Suitable for use with the IRIS & WIS equipments.

1.2 Description:

The kit is composed of :
A. Male luer lock connector for the connection to the Daily Kits.
B. One way valve
C. Needle free access with one way valve.
D. Male luer lock connector for the connection to the patient.
E. Collection tank for the liquid priming
Total lenght 50 cm. Volume = 0,7 ml
Materials: Polyethylene, ABS, PVC DEHP FREE, Polyurethane, Silicone, PTFE. **The device is DEHP and LATEX FREE.**
FOR THE USE FOLLOW THE MANUAL OF THE EQUIPMENT

1.3 Packaging:

The device is packed in pouch made of pharmaceutical grade paper and film, suitable to ETO sterilization. 100 pcs/box.
The product is supplied sterile and Pyrogen-free.

1.4 Sterilization:

The sterilization is individually performed through ETO exposition. The treatment is validated in conformity with Norms ISO 11135. The sterility is 5 years guaranteed. The product cannot be resterilized.

1.5 Quality Controls:

On receipt, each component is submitted to a dimensional and visual test for the verification of its conformity with the standards requirements, according to the internal quality procedures. On finished devices before the sterilization, following tests are performed: visual test, dimensional test, leak test, glueing sealing test and welding sealing test, according to internal quality procedures (IO01: glueing by solvent; IO02 single packaging; IC02: visual and dimensional test; IC03: air leak test; IC01: peeling test). The seal tests are performed by test machine at 1 bar pressure. Such test is performed by connecting the Female Luer Lock LL/F to the test machine and closing with caps the Male Luer Lock LL/M. The device is considered in conformity if within 10 seconds, has not a pressure decay major than 5 mmHg.

The devices just released by the sterilizator are tested for the packaging seal after the sterilization exposure. The sampling plans for above mentioned tests are in conformity with Norms UNI ISO 2859-1.The sterile finished devices are subjected to the sterility tests, pyrogen test, chemical toxicity test, ETO residue test in accordance with the monography E.P. IV ed. and ISO 10993-7 and biocompatibility test according to ISO 10993.

1.6 Manufacture and conformity:

The following device is manufactured according to GMP, moreover BTC Medical Europe has established and maintains a Quality System in conformity with the requirements of standards UNI EN ISO 9001 / ISO 13485. The device meets the essential requirements of the Directive 93/42/EEC concerning Medical Devices . The components are in conformity with ISO 594/1-2, E.P. current edition.

1.7 Classification:

Class IIa medical device, CE marked according to Directive 93/42/EEC, current editions and integrations concerning Medical Devices.

1.8 Disposal:

For the disposal, users have to apply the in force norms regulating the hospital waste disposal.

1.9 Storage:

Usual storage procedure, protect from moisture and keep away from light or heat sources.

1.10 Stability:

If correctly preserved and handled the medical device, maintains its own chemical – biological and physical characteristics all through its shelf life. The validity is reported on each single package. The expiry date is 5 years after release.