



Exclusive Distributor:



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1.1 Intended use:

Kit for the preparation and administration of radiopharmaceuticals drugs "FDG" to the patient.

Maximum Operating Pressure 3 bar = 40 psi

11.2 Description:

The kit is composed of :

1. 5 ml BD Syringe in PP Male Luer Lock
2. Pierceable cap in polysoprene
3. ABS Female Luer Lock

The particular configuration of the connector allows a speed and safe assemblage of the syringe to the equipment, guaranteeing the quality and costancy of sizes. **The device is 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 GAMMA sterilization. 150 pcs/box.

The product is supplied sterile and Pyrogen-free.

1.4 Sterilization:

The sterilization is performed through Gamma irradiation. The treatment is validated in conformity with Norms ISO 11137. The sterility is guaranteed for 5 years. 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. The device is considered in conformity if within 10 seconds, it has not a pressure decay major than 5 mmHg. The finished 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 .

1.7 Classification:

Class IIa medical device, CE marked according to Directive 93/42/EEC 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.