BTC Medical Europe S.r.l.
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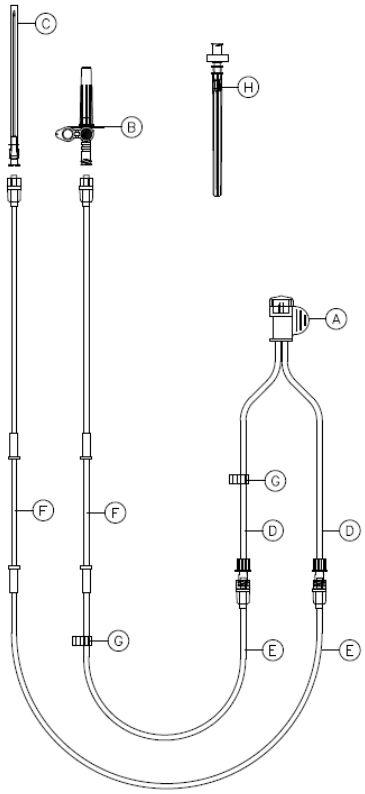
TECHNICAL SHEET

KIT ALTHEA / ALTHEA PC

REF: 38A1T20001 .01



CE 0051

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1.1 Intended use:

Kit for the fractioning of radiopharmaceuticals solutions. Suitable for Alteha and Althea PC cells.
Maximum Operating Pressure 7 bar (100 psi)

1.2 Descrizione:

The kit is composed of:

A. Double spike type Theodorico
B. Spike with air vent for the dilution solution
C. Solution needle 18G (Ø1,2 x 90 mm)
D. No. 2 PVC DEHP FREE extension line inner diameter 0.6 mm Length 38 cm
E. No. 2 PVC DEHP FREE extension line diameter 0.5x3.7 mm Total Length 115 cm
F. No. 2 PVC DEHP FREE pump segment diameter 0.5x3.7 mm
G. No. 2 tubes organizer
H. Vented needle 20G x70 mm with hydrophobic filter 0.2 µ and diameter 13 mm

Materials: PE, PP, ABS, PVC, PVC DEHP FREE, PVDF, Stainless steel.
The device is LATEX FREE.
FOR THE USE FOLLOW THE MANUAL OF THE EQUIPMENT.

1.3 Packaging:

The device is individually packed in triple pouch made of medical grade paper and PP/PE film, suitable to ETO sterilization.

1.4 Sterilization:

The sterilization is individually performed through ETO exposition. The treatment is validated in conformity with Norms ISO 11135. 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, gluing sealing test and welding sealing test, according to internal quality procedures (IO01: gluing by solvent; IO02 single packaging; IC01: peeling test; IC02: visual and dimensional test; IC03: air leak test The finished devices just released by the sterilizator are tested for the packaging seal after the sterilization exposure.
The seal tests are performed by test machine at 1 bar pressure. Such test is performed by connecting the device to the test machine and closing with caps the exits. The device is considered in conformity if within 10 seconds, has not a pressure decay major than 5 mmHg.

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 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 meet the requirements of the ISO 594/1-2, F.U. e F.Eu. 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.