+33 4.78.43.77.44
webmaster@cairlgl.fr

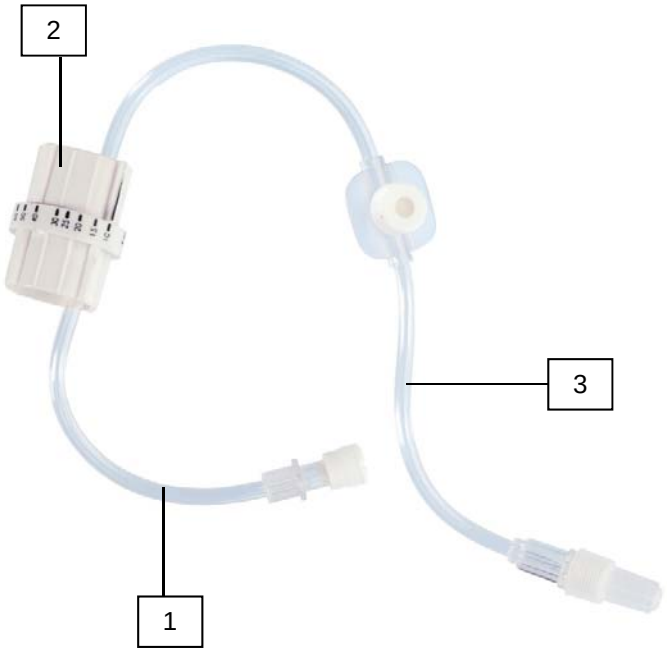
TECHNICAL SHEET
DF100

"DOSICAIR" FLOW REGULATOR WITH INJECTION SITE

RANGE: INFUSION
INTENDED USE: INFUSION WITH FLOW REGULATOR

REGULATORY INFORMATION
Sterile single use medical device
CE mark Class IIa
Notified Body : G-MED, number 0459
GMDN Nomenclature:

DEVICE DESCRIPTION:



MAIN COMPONENTS

1. Female luer lock extension line:
- Female luer lock connector in PVC with watertight cap in PE
- Tube in PVC, Ø 2.5 x 4.1 mm, L= 10 cm

2. "Dosicair" flow regulator: body in PC, joint in SI, graduation from 5 to 250 ml/h

3. Male luer lock extension line with injection site:
- Tube in PVC, Ø 2.5 x 4.1 mm, L= 20 cm
- Injection site: body in PP, cap in PVC, injection site un polisoprene
- Male luer lock connector in ABS and permeable protective cap in PE

DEHP (DOP), BBP, DBP, DIBP AND DHP are not part of composition of our products. The residual levels of these substance conforms to REACH regulation
ABSENCE OF LATEX

TECHNICAL FEATURES:

Residual volume: 2 ml

ISO 13485 – ISO 9001

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PRECAUTIONS FOR USE:
- Sterile unless package has been opened or damaged
- Do not re-sterilize
- Discard after single use.

Never use pliers. An excessive tightening can damage the luers and make disconnection difficult.
We recommend that periodic checks of the connection screw are made (at least once a day).

COMPATIBILITY OF MATERIALS:
All the components of the device are compatible with lipid emulsions and a great majority of classic disinfectants among which those on alcoholic base.

PRODUCTION:
- Injection and extrusion of components
- Automatic and manual assembly

QUALITY CONTROL:
- Visual control: Absence of scratches, smudges, breaks, tasks, deformations
- Dimensional control
- Functional control (pressure, water-tightness)

STERILIZATION:
Sterilization mode: **Ethylene oxide**
Validation and control of routine of the sterilization according to the International Standard ISO 11135.

CAIR LGL did not design this device to be reprocessed or reused, and therefore cannot verify that reprocessing can clean and/or sterilize or maintain the structural integrity of the device to ensure patient and/or user safety.

PRESERVATION
Expiry date: 59 months

STORAGE
In a clean and dry zone, shielded from the light, the temperature of which is between +5 and +40°C.

ELIMINATION
Elimination in a specialized container consisting of contaminated waste for incineration.

UNIT OF USE:
Blister: 1 face paper, 1 face transparent.
Packaging: 50 per carton.

ABBREVIATIONS: ABS: Acrylonitrile butadiene styrene ; ASA: Acrylonitrile Styrene Acrylate ; PA: Polyamide ; PC: Polycarbonate ; PE: Polyethylene ; PI: Polyisoprene ; POM: Polyacetale ; PP: Polypropylene ; PS: Polystyrene ; PU: Polyurethane ; PVC: Polyvinyl chloride ; SAN: Acrylonitrile styrene ; SI: Silicone ; SB: Styrene butadiene.
REACH: European regulation concerning the registration, evaluation, authorization and restriction of chemicals. Communication of information about concerned substances is mandatory if greater than 0,1% weight/weight.

CE 0459