ALLIANCE
Breathing life into medicines

Alliance Pharma S.r.l.
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EU DECLARATION OF CONFORMITY

Legal manufacturer: Alliance Pharma S.r.l.
Address: Viale Restelli 5, 20124 Milan, Italy

Declare under our sole responsibility that the product:

UDI DI: N/A

Product/trade names: OptiFlo G / OptiFlo R / OptiFlo S

Contisol G / Contisol R / Contisol S

Product codes, catalogue numbers or other references:

Code	Product Name	Size / Format	Carton Quantity
CSG50 / CSG100	OptiFlo G	50ml / 100ml	12
CSR50 / CSR100	OptiFlo R	50ml / 100ml	12
CSS50 / CSS100	OptiFlo S	50ml / 100ml	12
SOL50G / SOL100G	Contisol G	50ml / 100ml	12
SOL50R / SOL100R	Contisol R	50ml / 100ml	12
SOL50S / SOL100S	Contisol S	50ml / 100ml	12

Intended use:

The products are intended for use as part of a managed programme for the maintenance of in-dwelling urinary catheters. The catheter is inserted into the urethra to allow the bladder to drain into a collection bag worn by the patient; normally they will be inserted by a nurse in patients having incontinence problems caused by obstruction (in the urethra), urinary retention, severe impairment or terminal illness.

Optiflo / Contisol G and R	Optiflo / Contisol S
Solutions G and R are designed to help keep the catheter free of deposits, which might otherwise lead to blockage and infections in the bladder. These products can also assist in the removal of crystal deposits that have already built up in the catheter.	Solution S is designed to help keep the catheter free of debris, which might otherwise interfere with its normal function. This solution can also be used to help clear debris from the bladder.

Risk Class: Class I Sterile (Rule 5, indent 1)

Conformity assessment procedure: Annex V

Notified Body and Certificate no.: Eurofins (No. 0477), EPT 0477.MDD.17/2700

Additional information: N/A

- is in conformity with the European Directive 93/42/EEC, as amended;
- meets the essential requirements stated in Annex I of the European Directive 93/42/EEC, as amended.

Standard	Title
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices - Application of Risk Management to Medical Devices

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EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for In-vitro cytotoxicity
EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitisation
EN ISO 15223-1:2016	Medical Devices- Symbols to be used with Medical Device labels, labelling and information to be supplied General Requirements
EN ISO 1041:2008 +A1:2013	Information supplied by Manufacturers with Medical Devices
EN ISO 13408-1:2015	Aseptic processing of health care products - Part 1: General requirements
EN 556-2:2015	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for aseptically processed medical devices.
EN ISO 14644-1:2015 (Eu GMP)	Cleanrooms and associated controlled environments Classification of air cleanliness by particle concentration

Issued in Milan, Italy, on behalf of Alliance Pharma S.r.l.

Danilo Vergani

Firmato digitalmente da Danilo Vergani
Data: 2021.06.09 17:54:35 +02'00'

Date:

Name: Danilo Vergani

Function: Quality Director