

EC CERTIFICATE

According to Annex V of the Directive 93/42/EEC on Medical Devices

Production Quality Assurance System

Certificate Number: 2195-MED-2001701

Manufacturer: Atrion Medical Products, Inc.
1426 Curt Francis Road, Arab, Alabama 35016, USA

Product(s): (1) Sterile Inflation Device
(2) Sterile Locking Syringe
(3) Sterile Fluid Dispensing Syringe

Model(s): (1) QL10, QL14, QL20, QL25, QL38, QL40, QL60, QL20PR
(2) QL25, QL38
(3) QL4100, QL2030

Reference Report No: MM0779-P001-R01, MM0779-P001-R02

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex V, Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining sterile conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex V, Section 4 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements

This EC certificate is valid till 2022-02-06.

Issue Date: 2020-01-17



Rukiye BALKAN
Deputy General Manager