

EU QUALITY ASSURANCE CERTIFICATE

According to Annex XI-Part A of the Regulation (EU) 2017/745 on Medical Devices

Certificate No.: 2975-MED-2625202

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

Manufacturer's SRN: US-MF-000001944

Authorized Representative: Emergo Europe
Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands
SRN: NL-AR-000000116

Device Information: See Section 2

Report No.: MD0023-P001-R01

Specific Conditions or Limitations: N/A

Revision History: See Section 3

SZUTEST Konformitätsbewertungsstelle GmbH, Notified Body 2975, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex XI Part A, Section 6 of the Regulation (EU) 2017/745 on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Regulation. The approved quality system is subject to surveillance pursuant to Annex XI Part A Section 7 of the Regulation and unannounced site audits.

The Report, numbered above, summarizes the result of the conformity assessment and includes references to the relevant CS, harmonized standards sampled/reviewed technical documentation and test reports.

SZUTEST Konformitätsbewertungsstelle GmbH must be informed of any substantial changes in the design and/or construction of the mentioned device(s).

First Issue Date: 09-09-2026
Revision Date: 09-09-2026
Revision No.: 00
Validity Date: 08-09-2031



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-089




Mehmet IŞIKLAR
General Manager

This certificate can be validated by scanning the QR code or entering necessary information at <https://public.szutest-germany.de/>

1 / 2

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Section 2 – Device Information

No	Device(s) / Device Group(s)	Basic UDI-DI	Risk Class
1	Sterile QL Inflation Device	0856877002QLINFCK	Is The scope of certification is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.
2	Sterile QL Locking Syringe	0856877002QLLSBH	Is The scope of certification is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.

Section 3 – Revision History

Revision No	Revision Date	Identification of changes / definitions
00	09-09-2026	Initial Certification.