SZUTEST

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, QL40, QL60, QL20PR
(2) QL25, QL38
(3) QL4100, QL2030

Reference Report No: MM0779-P003-R01, MM0779-P003-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 safe 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 2024-05-26.

Issue Date: 2020-01-17
Revision No.: 02 Recertification
Revision Date: 2021-04-23

Rukiye BALKAN
Deputy General Manager

NOTIFIED BODY CONFIRMATION LETTER
No: MD0023-CL-01

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 and implementing Regulation (EU) 2023/1194 amending implementing Regulation (EU) 2022/2346 as regards the transitional provisions for certain medical devices.

This letter confirms that **SZUTEST Konformitätsbewertungsstelle GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2975** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Company Name	Atrion Medical Products, Inc.
Address	1426 Curt Francis Road, Arab, Alabama 35016, USA
SRN Number (if available)	US-MF-000001944

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded, and for which the SZUTEST Konformitätsbewertungsstelle GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but SZUTEST Konformitätsbewertungsstelle GmbH has not yet taken responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance with the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 31 December 2027 for Class III devices and Class IIb implantable devices excluding well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR
- 31 December 2028 for Annex XVI products which do not require a clinical investigation.
- 31 December 2029 for Annex XVI products which require a clinical investigation.

On behalf of SZUTEST Konformitätsbewertungsstelle GmbH,

MEHMET IŞIKLAR
General Manager

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To check the validity of this confirmation letter please scan the barcode. To manually check, go to https://public.szutest-germany.de/ use the first 3 digits of the manufacturer name and confirmation letter No. For further information please contact md_confirmation@szutest-germany.de

Table 1: Devices covered by this letter and for which SZUTEST Konformitätsbewertungsstelle GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (Under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Inflation Device	Class I device placed on the market in a sterile condition	Same	Certificate #1; 2195-MED-2001701 Revison No:02 Revision Date: 23.04.2021 Issue Date:17.01.2020 Expiry Date: 26.05.2024 Szutest Uygunluk Değerlendirme A.Ş
Locking Syringe	Class I device placed on the market in a sterile condition	Same	Certificate #1; 2195-MED-2001701 Revison No:02 Revision Date: 23.04.2021 Issue Date:17.01.2020 Expiry Date: 26.05.2024 Szutest Uygunluk Değerlendirme A.Ş
Fluid Dispensing Syringe	Class I devices with a measuring function	Same	Certificate #1; 2195-MED-2001701 Revison No:02 Revision Date: 23.04.2021 Issue Date:17.01.2020 Expiry Date: 26.05.2024 Szutest Uygunluk Değerlendirme A.Ş

Table 2: Devices covered by this letter and for which SZUTEST Konformitätsbewertungsstelle GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (Under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	*N/A*	*N/A*	*N/A*

Confirmation Letter Revision History

Date	Version of the letter	Action
2024/02/01	MD0023-CL-01	Initial issue
2024/09/27	MD0023-CL-01	The products have been transferred from Table-2 to Table-1