TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60136480 0001

Report No.: 12031472 005

Manufacturer:
ASTEC CO., LTD.
4-6-15 Minamizato, Shime, Kasuya
Fukuoka, Fukuoka-ken
811-2207 Japan

Products:
- In-Vitro Fertilization Equipment: Embryo Incubator

Expiry Date: 2024-01-25

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-05-13

Date: 2019-05-13

Notified Body

D. Swiatko

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

ASTEC CO., LTD.
4-6-15 Minamizato, Shime, Kasuya
Fukuoka, Fukuoka-ken
811-2207 Japan

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Service of In-Vitro Fertilization Equipment: Embryo Incubator

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2019-05-13
Certificate Registration No.:	SX 60136476 0001
An audit was performed. Report No.:	12031472 002
This Certificate is valid until:	2022-01-25

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2019-05-13

D. Swiatko

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