



EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. CE 575680
Issued To: **BIRR Biosciences B.V.**
Bergseweg 4
3633 AK Vreeland
The Netherlands

In respect of:

The manufacture of sterile micro-pipettes and puncture needles and sets for assisted reproductive technology and obstetrics; sterile foetal blood sampling kits; sterile pipettes, containers, tubes, dishes and serological pipettes for in-vitro fertilization procedures.

Those aspects of Annex V concerned with securing and maintaining the sterility of laboratory medical devices and catheters for assisted reproductive technology and obstetrics; and operating theatre equipment covers.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-05-16**

Date: **2021-05-07**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 575680

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Device code	Device name	Intended purpose per IFU
Class IIa		
MD 0109	Follicle puncture needles and sets	---
MD 0109	Pasteur and micro glass pipettes	---
MD 0109	IVF culture dishes (plastic)	---
MD 0109	IVF pipettes, tubes and containers (plastic)	---
MD 0106	Foetal blood sampling devices	---
Class Is		
MD 0109	IUI catheters	---
MD 0109	Aluminium secretion collection cup	---
MD 0100	Ultrasound probe cover	---
MD 0100	Cable cover	---

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