

# 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: **2020-03-20**

Expiry Date: **2021-05-15**

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

## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 575680**  
Date: **2020-03-20**  
Issued To: **BIRR Biosciences B.V.**  
**Bergseweg 4**  
**3633 AK Vreeland**  
**The Netherlands**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Almed B.V Dieselstraat 3 7903 AR Hoogeveen The Netherlands	<b>Manufacture Packaging</b>
Inpakomed BV Industrieweg 13A 1566 JN Assendelft The Netherlands	<b>Manufacture Packaging</b>
Sarstedt AG & Co. Sarstedtstraße 1 Nümbrecht 51588 Germany	<b>Manufacture Packaging</b>
Synergy Health AST, Venlo Faunalaan 38 5928 RZ Venlo The Netherlands	<b>ETO Sterilization</b>

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**Subcontractor:**

**Service(s) supplied**

Synergy Health Ede B.V.  
Morsestraat 3  
6716 AH Ede  
The Netherlands

**Gamma Sterilization**

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# EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
16 May 2016	8488492	First issue, transfer from another Notified Body.
17 March 2017	8652655	The addition of Sarstedt AG&Co. in Nümbrecht, Germany for the service of manufacture and packaging. The revision of the scope of certification to bring in line with BSI procedure.
11 February 2019	8544581	Traceable to NB 0086.
13 May 2019	9753148	Addition of subcontractor Inpakomed BV, Industrieweg 13a, 1566 JN Assendelft, The Netherlands for Manufacture and Packaging.
Current	9788259	Change of company name and address to BIRR BioSciences BV, Bergseweg 4, 3633 AK Vreeland, The Netherlands.

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.