By Royal Charter

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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EC Certificate - Production Quality Assurance

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**

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

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

List of Significant Subcontractors

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

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

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