

# EC Certificate - Production Quality Assurance

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

**No.** CE 672663  
Issued To: **Hunter Scientific Limited**  
**Unit 1, Priors Hall**  
**Widdington**  
**Saffron Walden**  
**Essex**  
**CB11 3SB**  
**United Kingdom**

In respect of:

**Manufacture and final inspection of sterile Pasteur pipettes for In Vitro Fertilisation.**

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: **2018-08-13**

Date: **2020-11-16**

Expiry Date: **2023-08-12**

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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 672663

Issued To:

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Number	Device Name	Intended purpose per IFU
<b>Class IIa</b>		
MD 0109	Pasteur pipettes	---

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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.

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## List of Significant Subcontractors

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

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Advena Limited Tower Business Centre 2nd Floor, Tower Street Swatar BKR 4013 Malta	<b>EU Representative</b>
Riverside Medical Packaging Company Ltd Newmarket Drive Derby DE24 8SW United Kingdom	<b>Packaging</b>
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Thorne) 1 Alpha Court Capitol Park Thorne Doncaster DN8 5TZ United Kingdom	<b>ETO Sterilization</b>

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# EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 672663**  
 Date: **2020-11-16**  
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Date	Reference Number	Action
13 August 2018	8727700	First Issue.
18 February 2019	8995683	Traceable to NB 0086.
Current	9719751	Addition of device schedule table. Addition of EU rep.

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