By Royal Charter

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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Supplementary Information to CE 672663

Issued To:

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Unit 1, Priors Hall
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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0109	Pasteur pipettes	---

First Issued: **2018-08-13** Date: **2020-11-16** Expiry Date: **2023-08-12**

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List of Significant Subcontractors

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

Certificate No:	**CE 672663**
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Subcontractor:	**Service(s) supplied**
Advena Limited Tower Business Centre 2nd Floor, Tower Street Swatar BKR 4013 Malta	**EU Representative**
Riverside Medical Packaging Company Ltd Newmarket Drive Derby DE24 8SW United Kingdom	**Packaging**
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Thorne) 1 Alpha Court Capitol Park Thorne Doncaster DN8 5TZ United Kingdom	**ETO Sterilization**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 672663**
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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.