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By Royal Charter

EC Certificate - Product Quality Assurance

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

No. **CE 678314**

Issued To: **Neotech Products LLC**
28430 Witherspoon Parkway
Valencia
CA 91355
USA

In respect of:

The final Inspection and testing of non-sterile, single use nasal cannula for infant, neonate and pediatric patients in respiratory use.

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

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

Albert Roossien, Regulatory Lead

First Issued: **2018-05-09** Date: **2019-02-04** Expiry Date: **2023-05-08**

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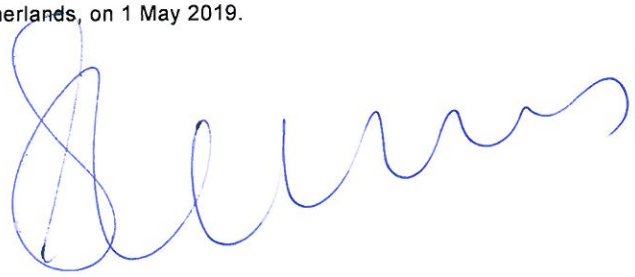
Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the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

Seen for the legalisation of the electronic signature of Mr. Albert Roossien, by me mr. August Johannes Avenarius, civil law notary in Amsterdam on 1 May 2019.

This statement does not refer to the contents of the attached documentation and may only be relied upon on the express condition that any issues of interpretation or liability there under, will be governed by Dutch law and are subject to the terms and conditions of Civilence B.V. as available on www.civilence.com. These terms and conditions provide for a limitation of liability.

Signed in Amsterdam, The Netherlands, on 1 May 2019.



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

List of Significant Subcontractors

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

Certificate No:	**CE 678314**
Date:	**2019-02-04**
Issued To:	**Neotech Products LLC** **28430 Witherspoon Parkway** **Valencia** **CA 91355** **USA**

Subcontractor:	**Service(s) supplied**
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	**EU Representative**

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EC Certificate - Product Quality Assurance Certificate History

Certificate No: **CE 678314**

Date: **2019-02-04**

Issued To: **Neotech Products LLC**
28430 Witherspoon Parkway
Valencia
CA 91355
USA

Date	Reference Number	Action
09 May 2018	8375330	First issue.
Current	8788362	Traceable to 0086.

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