

EC Certificate - Product Quality Assurance

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

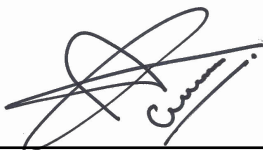
No. CE 678314
Issued To: Neotech Products LLC
28430 Witherspoon Parkway
Valencia
CA 91355
USA

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.

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

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