

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 649251**

Issued To:

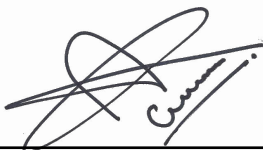
**Alcresta Therapeutics, Inc.
One Newton Executive Park
Suite 100
Newton
Massachusetts
02462
USA**

In respect of:

The design, development and manufacture of non-sterile, enteral feeding inline cartridge (lipase).

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 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: **2018-05-11**Date: **2019-02-15**Expiry Date: **2023-05-10****...making excellence a habit.™**

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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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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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

Certificate No: **CE 649251**
Date: **2019-02-15**
Issued To: **Alcresta Therapeutics, Inc.
One Newton Executive Park
Suite 100
Newton
Massachusetts
02462
USA**

Subcontractor:	Service(s) supplied
Alcresta 12 Michigan Drive Natick Massachusetts 01760 USA	Design
Amano Enzyme Inc 2-7-1 Chome Nishiki, Naka-ku Nagoya Aichi 460-8630 Japan	Crucial Supplier
Arran Chemical Company Monksland Industrial Estate Athlone Co. Roscommon N37 DN24 Ireland	Crucial Supplier

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Subcontractor:

Service(s) supplied

Bridgemedica, LLC
111 Forbes Boulevard, Suite 101
Mansfield
Massachusetts
02048
USA

**Manufacture
Packaging**

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

EU Representative

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Certificate History

Certificate No: **CE 649251**
 Date: **2019-02-15**
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Date	Reference Number	Action
11 May 2018	8472731	First Issue.
Current	8899144	Traceable to NB 0086.

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