

# EC Certificate - Full Quality Assurance System

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

**No.** **CE 655935**  
**Issued To:** **Novoxel GmbH**  
**Gatower Str. 124**  
**13595 Berlin**  
**Germany**

In respect of:

**Design and manufacture of a Thermo-Mechanical Ablation device for the treatment of actinic keratosis.**

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: **2016-08-11**

Date: **2019-02-18**

Expiry Date: **2021-06-24**

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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 II excluding Section 4

## List of Significant Subcontractors

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

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Date: **2019-02-18**  
Issued To: **Novoxel GmbH**  
**Gatower Str. 124**  
**13595 Berlin**  
**Germany**

**Subcontractor:**

**Service(s) supplied**

Novoxel Ltd  
43 Hamelaha St  
Netanya  
4250573  
Israel

**Design**

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## Certificate History

Certificate No: **CE 655935**  
 Date: **2019-02-18**  
 Issued To: **Novoxel GmbH**  
**Gatower Str. 124**  
**13595 Berlin**  
**Germany**

Date	Reference Number	Action
11 August 2016	8555131	Initial issue. Mirror Cert for CE 643960.
20 September 2017	8768909	Change of Novoxel GmbH's address from 32 Paul-Klee St., Landshut, 84034, Germany to Gatower Str. 124, Berlin, 13595, Germany.
Current	8471050	Traceable to NB 0086.

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