



By Royal Charter

UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

No. **UKCA 746301**

Issued To:
Novoxel Ltd.
43 Hamelaha St.
Netanya
4250573
Israel

In respect of:

Design and manufacture of Thermo-Mechanical Ablation devices for the treatment of actinic keratosis

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class III products an Annex II (modified as described above) Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-06-08**

Date: **2021-06-23**

Expiry Date: **2026-06-24**

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000

Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK.
A member of BSI Group of Companies.

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Supplementary Information to UKCA 746301

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Device code	Device Name	Intended purpose per IFU
Class IIa		
MD 1104	Thermo-mechanical ablation devices	---

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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

Certificate No: **UKCA 746301**

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Subcontractor:

Service(s) supplied

Qserve Group UK, Ltd.
49 Greek Street Soho
London
W1D 4EG
United Kingdom

UK Responsible Person

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UKCA Certificate - Full Quality Assurance System Certificate History

Certificate No: **UKCA 746301**
Date: **2021-06-23**
Issued To: **Novoxel Ltd.
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Date	Reference Number	Action
2021 June 08	3405866	First Issue; Traceable to CE 643960.
Current	3479309	Re-Issued – Certificate Renewal.

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