By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 752250 R000

Manufacturer: Novoxel GmbH

Address:
Gatower Str. 124
13595 Berlin
Germany

Single Registration Number: DE-MF-000012740

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

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

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2025-01-02**

Current Issue Date: **2025-01-02**

Starting Validity Date: **2025-01-02**

Expiry Date: **2030-01-01**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Thermo-Mechanical Ablation systems (including back-unit and handpieces) for the treatment of actinic keratosis.	Class IIa

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3478193	Issued

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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