

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]

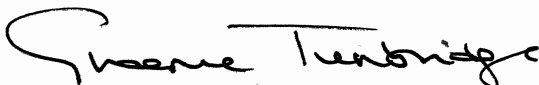
No. **UKCA 781559**
Issued To: **Nissha Medical Technologies Limited**
Torbay Business Park
Woodview Road
Paignton
Devon
TQ4 7HP
United Kingdom

In respect of:

Design, manufacture and final inspection of neutral electrodes for HF surgery.

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):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issued: **2023-03-23**

Date: **2025-03-27**

Expiry Date: **2030-04-05**

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Supplementary Information to UKCA 781559

Issued To:

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Device code	Device name	Intended purpose per IFU
Class IIb		
MD 1104	Electrosurgical diathermy system return electrode, single use, non-sterile	Self-adhesive, ready-to use disposable neutral electrodes used as an accessory for monopolar HF-surgery.

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Certificate History

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Date	Reference Number	Action
2023-03-23	3794723	First Issue; Traceable to CE 724262
Current	30366885	Certificate Renewal

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