



### 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. Issued To: UKCA 781559 Nissha Medical Technologies Limited Torbay Business Park Woodview Road

Vorbay 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 Medical Devices

First Issued: 2023-03-23

Date: 2023-03-23

Expiry Date: 2025-04-05

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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 781559**

Issued To:

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Device code	Device Name	Intended purpose per IFU	
Class IIb		NUM AN CEASE	
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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# UKCA Certificate - Full Quality Assurance System Certificate History

Certificate No: Date:

Issued To:

UKCA 781559 2023-03-23 Nissha Medical Technologies Limited Torbay Business Park Woodview Road Paignton Devon TQ4 7HP United Kingdom

Date	Reference Number	Action
Current	3794723	First Issue; Traceable to CE 724262



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