By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 724262**

Issued To: **Nissha Medical Technologies Ltd.**
Torbay Business Park
Woodview Road
Paignton
TQ4 7HP
United Kingdom

In respect of:

Design and Manufacture of neutral electrodes for HF surgery.

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):

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2020-04-06** Date: **2021-01-20** Expiry Date: **2024-05-26**

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Supplementary Information to CE 724262

Issued To:

Nissha Medical Technologies Ltd.
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Number	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.

First Issued: **2020-04-06** Date: **2021-01-20** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 724262**

Date: **2021-01-20**

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Date	Reference Number	Action
06 April 2020	3171977	First issue
06 April 2020	3171977	Reissued due to incorrect postcode
10 December 2020	3338415	Addition of EU Representative.
20 January 2021	3367629	Added subcontractor CEA Global Dominicana d.b.a Nissha Medical Technologies.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
22 October 2021	3556883	Removed subcontractor Tyrolmed. Change of EC Rep address to Boulevard de la Paix, 23-25, Cergy, 95800, France.
29 March 2023	3893943	Removal of subcontractor - CEA Global Dominicana d.b.a Nissha Medical Technologies, Solares 8 & 9 Manzana 5A, Zona Franca Industrial San Pedro de Macoris, Dominican Republic. Removal of subcontractor listings.

Inspiring trust for a more resilient world.

29 March 2023

Nissha Medical Technologies Ltd.
Torbay Business Park
Woodview Road
Paignton
TQ4 7HP
United Kingdom

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 724262	93/42/EEC Annex II excluding Section 4	3893943	Removal of subcontractor - CEA Global Dominicana d.b.a Nissha Medical Technologies, Solares 8 & 9 Manzana 5A, Zona Franca Industrial San Pedro de Macoris, Dominican Republic. Removal of subcontractor listings.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

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