

# 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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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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## Supplementary Information to CE 724262

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Number	Device Name	Intended purpose per IFU
<b>Class IIb</b>		
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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## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
CEA Global Dominicana d.b.a Nissha Medical Technologies Solares 8 & 9 Manzana 5A Zona Franca Industrial San Pedro de Macoris Dominican Republic	<b>Manufacture</b>
NISSHA MEDICAL TECHNOLOGIES SAS Z.A. des Boutries 12 rue des Cayennes 78700 Conflans Sainte Honorine France	<b>EU Representative</b>
TYROLMED GmbH Egger-Lienz-Straße 1d 6020 Innsbruck Austria	<b>Development Manufacture</b>

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## Certificate History

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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.
Current	3367629	Added subcontractor CEA Global Dominicana d.b.a Nissha Medical Technologies.

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