

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: **2020-04-06**

Expiry Date: **2024-05-26**

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Page 1 of 2

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

Issued To:

**Nissha Medical Technologies Ltd.
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Number	Device Name	Intended purpose per IFU
Class IIb		
NBOG 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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Torbay Business Park
Woodview Road
Paignton
TQ4 7HP
United Kingdom

Subcontractor:

Service(s) supplied

TYROLMED GmbH
Egger-Lienz-Straße 1d
6020 Innsbruck
Austria

Development
Manufacture

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: CE 724262
Date: 2020-04-06
Issued To: Nissha Medical Technologies Ltd.
 Torbay Business Park
 Woodview Road
 Paignton
 TQ4 7HP
 United Kingdom

Date	Reference Number	Action
06 April 2020	3171977	First issue
Current	3171977	Reissued due to incorrect postcode

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