

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. CE 703922
Issued To: **Nissha Medical Technologies Ltd.**
Torbay Business Park
Woodview Road
Paignton
Devon
TQ4 7HP
United Kingdom

In respect of:

Those aspects of Annex V related to metrology in the manufacture of recording charts with a measuring function for cardiology and foetal monitoring systems.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **2022-08-15**

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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.

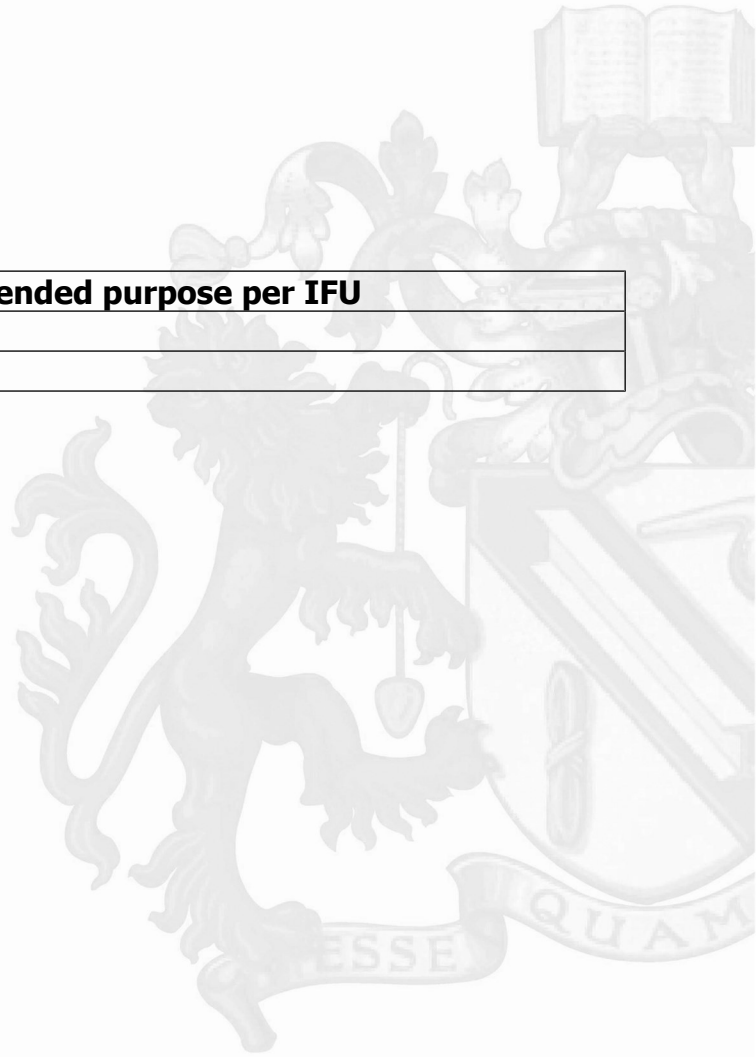
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Supplementary Information to CE 703922

Issued To:

**Nissha Medical Technologies Ltd.
 Torbay Business Park
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Number	Device Name	Intended purpose per IFU
Class Im		
NBOG MD 0104	Recording charts	N/A



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Page 2 of 2

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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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Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

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Date: **2020-04-06**
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Torbay Business Park
Woodview Road
Paignton
Devon
TQ4 7HP
United Kingdom

Subcontractor:

Service(s) supplied

Graphic Controls
d.b.a. Nissha Medical Technologies, Vermed, Biomedical
Innovations
400 Exchange St,
Buffalo,
New York 14204,
United States

Manufacture

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: CE 703922
Date: 2020-04-06
Issued To: Nissha Medical Technologies Ltd.
Torbay Business Park
Woodview Road
Paignton
Devon
TQ4 7HP
United Kingdom

Date	Reference Number	Action
Current	9685181	First issue based on existing certificate CE 669461.

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Page 1 of 1

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