

EC Certificate - Full Quality Assurance System

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

No. CE 674683
Issued To: Sports Art Industrial Co., Ltd.
No. 11, Gong Huan Rd.
Annan Dist.
Tainan City
70955
Taiwan

In respect of:

Design and Manufacture of Intelligently Controlled Assistive Rehabilitation Elliptical

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: **2020-08-28**

Date: **2020-08-28**

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.

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Supplementary Information to CE 674683

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NBOG Code(s)	Device Name	Intended purpose per IFU
Class IIa		
MD 1108	ICARE - Intelligently Controlled Assistive Rehabilitation Elliptical	---

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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 II excluding Section 4

List of Significant Subcontractors

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

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Subcontractor:

Service(s) supplied

Kernten Sport GmbH
Strada Cantonale 42
San Vittore
CH -6534
Switzerland

EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 674683**
 Date: **2020-08-28**
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Date	Reference Number	Action
Current	8744596	First issue.

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