

# EC Certificate - Full Quality Assurance System

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

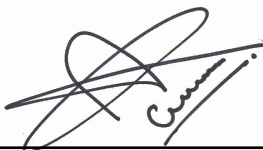
**No.** CE 524859  
**Issued To:** **CoolSystems, Inc**  
**dba Game Ready®**  
**1800 Sutter Street**  
**Suite 500**  
**Concord**  
**California**  
**94520**  
**USA**

In respect of:

**The design and manufacture of cold, heat, rapid contrast and intermittent pneumatic compression therapy systems for orthopaedic rehabilitation use.**

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):



Albert Roossien, Regulatory Lead

First Issued: **2008-03-26**

Date: **2019-02-05**

Expiry Date: **2023-03-25**

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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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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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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Emergo Prinsessegracht 20 2514 AP The Hague The Netherlands	<b>EU Representative</b>
PRIDE Industries 10030 Foothills Blvd. Roseville California 95747 USA	<b>Manufacture</b>
Spectrum Assembly Incorporated 6300 Yarrow Drive Carlsbad California 92011 USA	<b>Manufacture</b>

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# EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
26 March 2008	7103946	First Issue.
28 April 2008	7199631	Re-Issue to correct Subcontractor Address.
13 October 2011	7283056	Certificate re-issue due to 'PRIDE Industries, 10030 Foothills Blvdl, Roseville, CA 95717, USA' added as a significant subcontractor.
19 December 2011	7778001	Reissue due to change of company address from '1201 Marina Village Parkway, Alameda, California' to '1800 Sutter Street, Concord, California'. Addition of "CoolSystems Inc, Concord, USA" for Warehousing and "Emergo Europe, 2513 BH, Netherlands" as EU Representative. Removal of "Flextronics International Limited" from the list of significant subcontractors.
26 March 2013	7943664	Certificate Renewal. Upgrade to an Annex II and adding 'design' to the scope.

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Date	Reference Number	Action
08 August 2017	8651609	Extension to scope, from "The design and manufacture of cool and compression therapy systems for orthopaedic rehabilitation use" to "The design and manufacture of cold, heat, rapid contrast and intermittent pneumatic compression therapy systems for orthopaedic rehabilitation use." Addition of subcontractor Spectrum Assembly Incorporated for the services of manufacture. Removal of subcontractor CoolSystems, Inc, dba Game Ready®, 5165 Commercial Circle, Suite B, Concord, California, 94520, USA. Change of address for EU Rep Emergo Europe from Molenstraat 15, 2513 BH, Hague, The Netherlands to Prinsessegracht 20, 2514 AP The Hague, The Netherlands.
19 March 2018	8845589	Certificate Renewal
Current	7782033	Traceable to NB 0086.