By Royal Charter

# 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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# EC Certificate - Full Quality Assurance System

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:

| | |
|---|---|
| Certificate No: | **CE 524859** |
| Date: | **2019-02-05** |
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| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Emergo<br>Prinsessegracht 20<br>2514 AP The Hague<br>The Netherlands | **EU Representative** |
| PRIDE Industries<br>10030 Foothills Blvd.<br>Roseville<br>California 95747<br>USA | **Manufacture** |
| Spectrum Assembly Incorporated<br>6300 Yarrow Drive<br>Carlsbad<br>California<br>92011<br>USA | **Manufacture** |

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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.<br>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."<br>Addition of subcontractor Spectrum Assembly Incorporated for the services of manufacture.<br>Removal of subcontractor CoolSystems, Inc, dba Game Ready®, 5165 Commercial Circle, Suite B, Concord, California, 94520, USA.<br>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. |