By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 582293**

Issued To: **Bolder Surgical**
331 104th Street, Ste. 200
Louisville
Colorado
80027
USA

In respect of:

Design and manufacture of electrosurgical ligation generator, sterile sealer and sterile surgical staplers and reloads.

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: **2015-03-03** Date: **2020-01-23** Expiry Date: **2024-05-26**

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Supplementary Information to CE 582293

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Number	Device Name	Intended purpose per IFU
Class IIb		
GMDN 57944 MD 1104	JustRight Sealer	The JustRight Surgical® Vessel Sealing System is intended for use in open and laparoscopic general surgical procedures to seal blood vessels and vascular bundles up to and including 5 mm in diameter for use in adult and pediatric populations wherever vessel ligation is required.
GMDN 11490 MD 1104	JustRight™ Generator	
GMDN 59871 GMDN 35615 MD 0106 MD 0204	JustRight 5mm Stapler and 5mm Reload	The JustRight 5mm Stapler is intended for use in abdominal, gynecologic, pediatric, and thoracic surgery for resection, transaction and creation of anastomosis.

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List of Significant Subcontractors

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

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Subcontractor:	**Service(s) supplied**
Healthlink Europe Services BV De Tweeling 20-22 5215 MC 's-Hertogenbosch The Netherlands	**EU Representative**
Primo Medical Group 75 Mill Street Stoughton Massachusetts 02072 USA	**Control of Sterilization** **Design** **Manufacture**
Sparton Medical Systems Colorado, LLC 4300 Godding Hollow Parkway Frederick Colorado 80504-9486 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 582293**

Date: **2020-01-23**

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Date	Reference Number	Action
03 March 2015	7770771	First Issue.
23 June 2015	8347696	Change of certificate address to, 'Just Right Surgical, 357 South McCaslin Boulevard, Louisville, CO 80027'.
05 April 2016	8500776	Addition of subcontractor, 'Sparton Medical Systems Colorado, LLC'. Clarification of which devices are sterile in scope. Added "Sterile" manufacture to Primo's subcontractor role.
03 January 2019	9653528	Changed address from 357 South McCaslin Boulevard, Louisville, CO, 80027, USA to current. Added control of sterilization to Primo Medical Group subcontractor. Added product listing matrix to comply with new scope requirements.
25 January 2019	8411218	Traceable to NB 0086.
Current	9751122	Manufacturer name change from JustRight Surgical, LLC to Bolder Surgical, LLC Administrative change to manufacturer's address from "331 104th Street, Ste. 200" to "331 S. 104th Street, Ste. 200" Renewal