By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 01945**

Issued To: **ArjoHuntleigh AB**
Hans Michelsensgatan 10
211 20 Malmö
Sweden

In respect of:

The design and manufacture of bathing systems incorporating hydrotherapy and hydrosound and associated disinfectants, pressure area management systems, intermittent compression systems and associated pumps, and washer disinfectors for non-invasive medical devices, vital signs monitors, fetal monitors, vascular blood flow monitors and associated sterile and non-sterile accessories.
Those aspects of Annex II concerned with the metrological requirements of weighing beds, patient lifting devices and bathing systems.

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: **1998-06-12** Date: **2021-04-12** Expiry Date: **2023-06-11**

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Supplementary Information to CE 01945

Issued To:

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Number	Device Name	Intended purpose per IFU
Class III		
---	Intraoperative Doppler Ultrasound Probes	See CE 727863
Class IIb		
MD 1302	Desktop Fetal Monitors with associated probes	Non-invasive and invasive monitoring of physiological parameters in pregnant women and fetuses
MD 1302, MD 1111	Vital Signs Monitors with associated probes and software	Monitoring of adult, paediatric and neonate physiological vital signs
Class IIa		
MD 1402	Bathing systems incorporating hydrotherapy and hydrosound	N/A
MD 0108	Disinfectant for bathing systems	N/A
MD 1109	Therapeutic surfaces and alternating pressure pumps	N/A

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MD 1103	Intermittent compression systems and associated pumps	N/A
Class IIa		
MD 1107	Washer disinfectors for non-invasive medical devices	N/A
MD 1302 MD 1111	Hand Held and Desktop Fetal Monitors with associated probes and software	N/A
MD 1302 MD 1111	Vascular Blood Flow Monitors with associated probes and software	N/A
Class Im		
MD 1109	Weighing beds	N/A
MD 1109	Patient lifting devices	N/A
MD 1402	Bathing systems	N/A

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List of Significant Subcontractors

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

Certificate No:	**CE 01945**
Date:	**2021-04-12**
Issued To:	**ArjoHuntleigh AB** **Hans Michelsensgatan 10** **211 20 Malmö** **Sweden**

Subcontractor:	**Service(s) supplied**
Andersen Caledonia Limited Caledonian House Phoenix Crescent Strathclyde Business Park Lanarkshire Bellshill ML4 3NJ UK	**ETO Sterilization**
Arjo (Suzhou) Co., Ltd. No. 158 Fangzhou Road Suzhou Industrial Park, Suzhou 215024 Jiangsu China	**Design** **Manufacture**
Arjo Dominican Republic SA Building 9 and 21, Parque Industrial Itabo S.A. Km 18 1/2 Carretera Sanchez 10903 Haina San Cristóbal Dominican Republic	**Design** **Manufacture**

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Subcontractor:	**Service(s) supplied**
ArjoHuntleigh Magog Inc. 2001, rue Tanguay Magog Québec J1X 5Y5 Canada	**Design** **Manufacture**
ArjoHuntleigh Polska Sp. z o.o. ul. Ks. Wawrzyniaka 2 62-052 Komorniki Poland	**Design** **Manufacture**
Huntleigh Healthcare Ltd 35 Portmanmoor Road Cardiff CF24 5HN United Kingdom	**Design** **Manufacture**
Mico AB Välingevägen 245 262 92 Ängelholm Sweden	**Crucial Supplier**

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Subcontractor:	**Service(s) supplied**
SHL Technologies Ltd. 2F., No. 313-1, Sec. 2, Nanshan Rd. Luzhu Dist. Taoyuan City 33852 Taiwan	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
12 June 1998	-	First Issue
08 December 1999	-	Addition of bathing systems to scope
28 October 2004	4570866	Five year renewal
02 June 2008	7217309	Certificate renewal
02 December 2011	7674488	Upgrade from Annex V to Annex II. Addition of disinfectants to scope. Change of legal manufacturer from Arjo Hospital Equipment AB manufacturing site in Eslov to ArjoHuntleigh AB corporate head office in Eslov. Extension to scope to include pressure area management systems, weighing beds, wound care products, intermittent compression systems and associated pumps, following transfers from other notified bodies in August 2011. Addition of ArjoHuntleigh sites in the UK, Poland, Canada and China, First Water Ltd and ArcRoyal Ltd as significant subcontractors.
26 March 2012	7803146	Certificate reissue due to relocation of the ArjoHuntleigh Luton site to Houghton Regis, Dunstable, UK
30 August 2012	7858461	Certificate reissue - corrections to significant subcontractor name/address formats

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Date	Reference Number	Action
28 May 2013	7918650	Certificate renewal. Removal of ArjoHuntleigh Dunstable, UK site as a significant subcontractor and addition of design as a subcontractor activity for ArjoHuntleigh site in Suzhou, China. Removal of First Water Ltd and ArcRoyal Ltd as significant subcontractors.
08 October 2013	8066205	Certificate reissue due to addition of ArjoHuntleigh Inc in San Antonio, Texas, USA as a significant subcontractor for design and removal of ArjoHuntleigh Cardiff, UK site
10 December 2013	8082205	Certificate reissue due to change to legal manufacturer address from Verkstadsvagen 5, 24138 Eslöv to Hans Michelsensgatan 10, 211 20 Malmö
06 May 2014	8136772	Certificate reissue due to change of address of ArjoHuntleigh Inc. from 4958 Stout Drive to 12625 Wetmore Rd., San Antonio, Texas, USA

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Date	Reference Number	Action
08 May 2015	8281577	Removal of Arjo Hospital Equipment AB, Sweden and ArjoHuntleigh Wednesbury, UK sites as significant subcontractors. Addition of VEPLAS RTM d.o.o as a significant subcontractor for manufacture, Synergy Health AST, Venlo as a significant subcontractor for EO sterilisation and Mico AB as a crucial supplier. Extension to scope to include Class I sterile intermittent compression garments.
10 March 2016	8468754	Addition of AccuMED Corp, EEZCARE Medical Corp., Joerns Healthcare Limited and SHL Healthcare Ltd as significant subcontractors for manufacture. Removal of wound care products from scope.
09 May 2017	8714310	Change of name of significant subcontractor AccuMED Corp to Getinge Dominican Republic SA.
16 January 2018	8866912	Change of scope to include washer disinfectors for non-invasive medical devices and removal of significant subcontractor EEZCARE Medical Corp.
24 April 2018	8895083	Certificate renewal and removal of significant subcontractor Joerns Healthcare Limited
27 February 2019	7780153	Traceable to NB 0086.

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Date	Reference Number	Action
01 August 2019	9629778	Removal of significant subcontractor ArjoHuntleigh Inc in San Antonio, Texas, USA. Change of name of significant subcontractors Getinge (Suzhou) Co., Ltd to Arjo (Suzhou) Co., Ltd, Getinge Dominican Republic SA to Arjo Dominican Republic SA and SHL Healthcare Ltd to SHL Technologies Ltd. Addition of device table.
21 May 2020	3125975	Extension to the previous certificate scope to add: "vital signs monitors, fetal monitors, vascular blood flow monitors and associated accessories". Products table updated with new devices. Addition of Huntleigh Healthcare Ltd as significant subcontractor for Design and Manufacture. Changes for significant subcontractor Arjo Dominican Republic S.A.: building 21 added to the address and design added as activity. Change of address for significant subcontractor SHL Technologies Ltd.

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Date	Reference Number	Action
08 October 2020	3291906	Reduction to the scope to remove: "Those aspects of Annex II concerned with securing and maintaining sterile conditions of intermittent compression garments." Products table updated for removal of class Is device. Removal of Synergy Health AST as subcontractor for ETO sterilization. Removal of "Diagnostic Products Division" from address of subcontractor Huntleigh Healthcare Ltd.
12 April 2021	3250923	Added sterile accessories to scope. Added subcontractor Andersen Caledonia Limited. Product Table updated to change Intraoperative Doppler Ultrasound Probe to Intraoperative Doppler Ultrasound Probes.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
30 July 2021	3498341	Amended - Removal of subcontractor for manufacture "VEPLAS RTM d.o.o."

Inspiring trust for a more resilient world.

30th of July 2021

ArjoHuntleigh AB
Hans Michelsensgatan 10
211 20 Malmö
Sweden

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	**Directive and Annex**	**Reference Number**	**Changes approved**
CE 01945	93/42/EEC Annex II excluding Section 4	3498341	Removal of subcontractor: VEPLAS RTM d.o.o. Cesta Simona Blatnika 11 3320 Velenje Slovenia

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

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