

# 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:

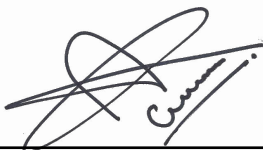
**The design and manufacture of bathing systems incorporating hydrotherapy and hydrosound and associated disinfectants, pressure area management systems, intermittent compression systems and associated pumps, and washer disinfectors for non-invasive medical devices.**

**Those aspects of Annex II concerned with the metrological requirements of weighing beds, patient lifting devices and bathing systems.**

**Those aspects of Annex II concerned with securing and maintaining sterile conditions of intermittent compression garments.**

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: **1998-06-12**

Date: **2019-02-27**

Expiry Date: **2023-06-11**

...making excellence a habit.™

Page 1 of 1

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.

# 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 01945**  
 Date: **2019-02-27**  
 Issued To: **ArjoHuntleigh AB**  
**Hans Michelsensgatan 10**  
**211 20 Malmö**  
**Sweden**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
ArjoHuntleigh Inc 12625 Wetmore Rd., Suite #308 San Antonio Texas 78247 USA	<b>Design</b>
ArjoHuntleigh Magog Inc. 2001, rue Tanguay Magog Québec J1X 5Y5 Canada	<b>Design</b> <b>Manufacture</b>
ArjoHuntleigh Polska Sp. z o.o. ul. Ks. Wawrzyniaka 2 62-052 Komorniki Poland	<b>Design</b> <b>Manufacture</b>

...making excellence a habit.™

# 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 01945**  
Date: **2019-02-27**  
Issued To: **ArjoHuntleigh AB**  
**Hans Michelsensgatan 10**  
**211 20 Malmö**  
**Sweden**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Getinge (Suzhou) Co., Ltd No. 158 Fangzhou Road Suzhou Industrial Park, Suzhou 215024 Jiangsu China	<b>Design</b> <b>Manufacture</b>
Getinge Dominican Republic SA Building 9, Parque Industrial Itabo S.A. KM 18 1/2 Carretera Sanchez 10903 Haina San Cristobal Dominican Republic	<b>Manufacture</b>
Mico AB Välingevägen 245 262 92 Ängelholm Sweden	<b>Crucial Supplier</b>

...making excellence a habit.™

# 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 01945**  
 Date: **2019-02-27**  
 Issued To: **ArjoHuntleigh AB**  
**Hans Michelsensgatan 10**  
**211 20 Malmö**  
**Sweden**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
SHL Healthcare Ltd No. 136, Kuo Sheng 2nd Street Taoyuan Dist. Taoyuan City 33060 Taiwan	<b>Manufacture</b>
Synergy Health AST, Venlo Faunalaan 38 5928 RZ Venlo Netherlands	<b>ETO Sterilization</b>
VEPLAS RTM d.o.o Cesta Simona Blatnika 11 3320 Velenje Slovenia	<b>Manufacture</b>

...making excellence a habit.™

# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01945**  
 Date: **2019-02-27**  
 Issued To: **ArjoHuntleigh AB**  
**Hans Michelsensgatan 10**  
**211 20 Malmö**  
**Sweden**

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

...making excellence a habit.™

Page 1 of 3

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.

# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01945**  
 Date: **2019-02-27**  
 Issued To: **ArjoHuntleigh AB**  
**Hans Michelsensgatan 10**  
**211 20 Malmö**  
**Sweden**

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

...making excellence a habit.™

Page 2 of 3

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.

# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01945**  
 Date: **2019-02-27**  
 Issued To: **ArjoHuntleigh AB**  
**Hans Michelsensgatan 10**  
**211 20 Malmö**  
**Sweden**

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
Current	7780153	Traceable to NB 0086.