By Royal Charter

UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

No. **UKCA 754820**

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

In respect of:

The design and manufacture of 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 Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class III products an Annex II (modified as described above) Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2021-10-05** Date: **2022-04-13** Expiry Date: **2023-06-11**

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Supplementary Information to UKCA 754820

Issued To:

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Device code	Device name	Intended purpose per IFU
Class III		
---	Intraoperative Doppler Ultrasound Probes	See UKCA 757250
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 1109	Therapeutic surfaces and alternating pressure pumps	N/A

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Device code	Device name	Intended purpose per IFU
MD 1103	Intermittent compression systems and associated pumps	N/A
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 Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

Certificate No:	**UKCA 754820**
Date:	**2022-04-13**
Issued To:	**ArjoHuntleigh AB** **Hans Michelsensgatan 10** **Malmö** **211 20** **Sweden**

Subcontractor:	**Service(s) supplied**
Andersen Caledonia Limited Caledonian House Phoenix Crescent Strathclyde Business Park Lanarkshire Bellshill ML4 3NJ United Kingdom	**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**
Arjo UK Ltd Houghton Hall Business Park Houghton Regis Beds LU5 5XF United Kingdom	**UK Responsible Person**
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**

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

Subcontractor:	**Service(s) supplied**
Huntleigh Healthcare Ltd 35 Portmanmoor Road Cardiff CF24 5HN United Kingdom	**Design** **Manufacture**
SHL Technologies Ltd. 2F., No. 313-1, Sec. 2, Nanshan Rd. Luzhu Dist. Taoyuan City 33852 Taiwan	**Manufacture**

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UKCA Certificate - Full Quality Assurance System Certificate History

Certificate No: **UKCA 754820**

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Date	Reference Number	Action
2021 October 05	3495045	First issue; Traceable to CE 01945.
Current	3619926	Removal of Class IIa bathing systems from certificate scope and device table as the indications were reduced and therefore bathing systems have been reclassified as Class Im.

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