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:

See certificate scope page.

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: **2023-11-16** Expiry Date: **2028-06-11**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.
This certificate was issued electronically and is bound by the conditions of the contract.

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000
Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK.
A member of BSI Group of Companies.

By Royal Charter

Certificate No: UKCA 754820

Certificate Scope:

Design, manufacture and final inspection of:
-non-sterile pressure area management systems
-non-sterile intermittent compression systems and associated pumps
-non-sterile washer disinfectors for non-invasive medical devices
-non-sterile vital signs monitors
-non-sterile fetal monitors
-non-sterile vascular blood flow monitors and associated sterile and non-sterile accessories

Those aspects of Annex II relating to metrology of weighing beds, patient lifting devices and bathing systems.

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Supplementary Information to UKCA 754820

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Device code	Device name	Intended purpose per IFU
Class III		
---	Intraoperative Doppler ultrasound probe	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, during the intrapartum and antepartum periods of pregnancy. The devices are intended for use in clinical and hospital-type facilities.
MD 1111	Centralised fetal monitoring software	Centralised monitoring of physiological parameters in pregnant women and fetuses and provides viewing, analysis & archiving of data sourced from fetal monitors.
MD 1302	Vital signs monitors with associated probes	Monitor physiologic status of Adult, Paediatric and Neonatal patients.
MD 1111	Centralised vital signs software	Centralised monitoring and management of Adult, Paediatric and Neonatal vital signs.

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Device code	Device name	Intended purpose per IFU
Class IIa		
MD 1109	Pressure area management systems and associated pumps	---
MD 1103	Intermittent compression systems and associated pumps	---
MD 1107	Washer disinfectors for non-invasive medical devices	---
MD 1302	Fetal and blood flow monitors with associated probes	---
Class Im		
MD 1109	Weighing beds	---
MD 1109	Patient lifting devices	---
MD 1402	Bathing systems	---

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UKCA Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
2021-10-05	3495045	First issue; Traceable to CE 01945.
2022-04-13	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.
Current	30000210	Certificate Renewal. Amendment to wording of the device schedule and scope.

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