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 bathing systems incorporating hydrotherapy and hydrosound, 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):

Gary E Slack, Senior Vice President Medical Devices

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

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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 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<br>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 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<br>MD 1111 | Hand Held and Desktop Fetal Monitors with associated probes and software | N/A |
| MD 1302<br>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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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]

# List of Critical Subcontractors and Crucial Suppliers

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

| | |
|---|---|
| Certificate No: | **UKCA 754820** |
| Date: | **2021-10-05** |
| Issued To: | **ArjoHuntleigh AB**<br>**Hans Michelsensgatan 10**<br>**Malmö**<br>**211 20**<br>**Sweden** |

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

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| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Arjo UK Ltd<br>Houghton Hall Business Park<br>Houghton Regis<br>Beds<br>LU5 5XF<br>United Kingdom | **UK Responsible Person** |
| ArjoHuntleigh Magog Inc.<br>2001, rue Tanguay<br>Magog<br>Québec<br>J1X 5Y5<br>Canada | **Design**<br>**Manufacture** |
| ArjoHuntleigh Polska Sp. z o.o.<br>ul. Ks. Wawrzyniaka 2<br>62-052 Komorniki<br>Poland | **Design**<br>**Manufacture** |

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

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# UKCA Certificate - Full Quality Assurance System Certificate History

Certificate No: **UKCA 754820**

Date: **2021-10-05**

Issued To: **ArjoHuntleigh AB**
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**Sweden**

| Date | Reference Number | Action |
|---|---|---|
| Current | 3495045 | First issue; Traceable to CE 01945. |

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