

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

**MDR 718928 R001**

**Manufacturer:** ArjoHuntleigh AB

**Address:**

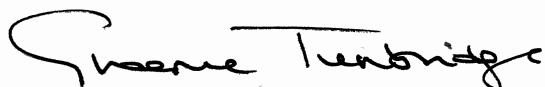
Hans Michelsensgatan 10  
211 20 Malmö  
Sweden

**Single Registration Number:** SE-MF-000000696

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2021-01-11**

Starting Validity Date: **2026-01-10**

Current Issue Date: **2025-12-17**

Expiry Date: **2031-01-10**

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

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80  
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.  
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## Device Schedule: Class III and Class IIb devices

<b>Class III</b>	<b>Intended purpose</b>
Intraoperative Doppler ultrasound probe	See MDR 781850
<b>Class IIb</b>	<b>Intended purpose</b>
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.
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.
Vital signs monitors with associated probes	Monitor physiologic status of Adult, Paediatric and Neonatal patients.
Centralised vital signs monitoring software	Centralised monitoring and management of Adult, Paediatric and Neonatal vital signs.

## Device Schedule: Class IIa, Custom-made and other devices

<b>Device(s)</b>	<b>Risk Classification</b>
Intermittent compression systems and associated pumps	Class IIa
Pressure area management systems and associated pumps	Class IIa
Washer disinfectors for non-invasive medical devices	Class IIa
Fetal and blood flow monitors with associated probes	Class IIa
Weighing beds	Class Im
Patient lifting devices	Class Im
Bathing systems	Class Im

For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.

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## Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference number	Action
2021-01-11	3083788	Issued
2021-12-02	3578498	Supplemented – Addition of device category “Pressure are management systems and associated pumps” Amended – Addition of SRN; Addition of subcontractors; Administrative update to prior history entry
2023-12-14	30000211	Supplemented – Addition of device categories: “Washer disinfectors for non-invasive medical devices” and “Fetal and blood flow monitors with associated probes”. Supplemented – Addition of device groups: “Desktop fetal monitors with associated probes”, “Centralised fetal monitoring software”, “Vital signs monitors with associated probes” and “Centralised vital signs monitoring software”. Supplemented – Addition of “Intraoperative Doppler ultrasound probe” device.
Current	30469363	Re-Issued – Certificate Renewal

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