EU Quality Management System Certificate

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

MDR 718928 R000

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 Medical Devices

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

Current Issue Date: **2023-12-14**

Starting Validity Date: **2023-12-14**

Expiry Date: **2026-01-10**

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Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
Intraoperative Doppler ultrasound probe	See MDR 781850

Class IIb	Intended purpose
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

Device(s)	Risk Classification
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
Current	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.

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