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 and Class IIb implantable devices an Annex IX Chapter II certificate is required.

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

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-01-11** Date: **2021-12-02** Expiry Date: **2026-01-10**

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Device Schedule: Class IIa and other devices

Device(s)	Risk Classification
Intermittent compression systems and associated pumps	Class IIa
Pressure area management systems and associated pumps	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
Current	3578498	Supplemented – Addition of device category "Pressure area management systems and associated pumps" Amended – Addition of SRN; Addition of subcontractors: Arjo Dominican Republic S.A. and SHL Technologies Ltd.; Administrative update to prior history entry

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List of Critical Subcontractors and Crucial Suppliers

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

MDR 718928 R000

Date: **2021-12-02**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Arjo (Suzhou) Co., Ltd. No. 158 Fangzhou Road Suzhou Industrial Park, Suzhou 215024 Jiangsu China	**Design** **Manufacture**
Arjo Dominican Republic S.A. Building 9&21 Parque Industrial Itabo SA Km 18 1/2 Carretera Sanchez 10903 Haina San Cristóbal Dominican Republic	**Design** **Manufacture**
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**
Huntleigh Healthcare Ltd 35 Portmanmoor Road Cardiff CF24 5HN United Kingdom	**Design** **Manufacture**

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List of Critical Subcontractors and Crucial Suppliers

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Date: **2021-12-02**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
SHL Technologies Ltd. 2F., No. 313-1, Sec. 2, Nanshan Rd. Luzhu Dist. Taoyuan City 33852 Taiwan	**Manufacture**

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