




Declaration of Conformity

Manufacturer	ArjoHuntleigh AB Hans Michelsensgatan 10 211 20 Malmö, Sweden
Single Registration Number	SE-MF-000000696
Declaration	ArjoHuntleigh AB as the manufacturer of the following medical devices, takes sole responsibility and declares conformity with the applicable provisions of Medical Device Regulation (EU) 2017/745 concerning medical devices.
Device Family Name	Sara Flex – HEB0xxx-xx
Intended Purpose	Mobile Lifter - Patient/Resident
Basic UDI-DI	5060693520112VK
Additional Information	Also complies with the following EU Legislation: Machinery Directive 2006/42/EC RoHS Directive 2011/65/EU
Risk Class and Rule	 Class I, Rule 13

APPROVED BY		
Title: Regulatory Affairs Specialist	Signature: 	Electronically signed by: Champa Patel Reason: I am signing as approver of this document Date: Oct 2, 2024 08:23 GMT+1
Name: Champa Patel	Date: 02-Oct-2024	
Title: Local Quality Manager	Signature: 	Electronically signed by: Melanie Chasse Reason: I am signing as approver of this document Date: Oct 2, 2024 07:11 EDT
Name: Mélanie Chassé	Date: 02-Oct-2024	

On behalf of ArjoHuntleigh AB: Place: Magog

100084269 - 01-Oct-2024

Final Audit Report


2024-10-02

Created:	2024-10-01 (Central European Summer Time)
By:	Joanie Masse (joanie.masse@arjo.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAUgZF6mEIU9RVn0E7GAANhXcnuJGqwXDO

"100084269 - 01-Oct-2024" History

 Document created by Joanie Masse (joanie.masse@arjo.com)

2024-10-01 - 8:19:51 PM GMT+2

 Document emailed to Champa Patel (Champa.Patel@arjo.com) for signature

2024-10-01 - 8:20:33 PM GMT+2

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2024-10-02 - 9:22:47 AM GMT+2

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Challenge: The user clicked on the signature field: 'Signature 2'.

2024-10-02 - 1:10:51 PM GMT+2

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Declaration of Conformity

Manufacturer	ArjoHuntleigh AB Hans Michelsensgatan 10 211 20 Malmö, Sweden
Single Registration Number	SE-MF-000000696
Declaration	ArjoHuntleigh AB as the manufacturer of the following medical devices, takes sole responsibility and declares conformity with the applicable provisions of Medical Device Regulation (EU) 2017/745 concerning medical devices, by Annex IX.
Device Family Name	Sara Flex – HEB1xxx-xx
Intended Purpose	Mobile Lifter - Patient/Resident
Basic UDI-DI	5060693520082W3
Risk Class and Rule	Class IM, Rule 13
Additional Information	Also complies with the following EU Legislation: Machinery Directive 2006/42/EC RoHS Directive 2011/65/EU as amend
Notified Body Name and Number	 <div> BSI Group The Netherlands B.V. Number: 2797 CE Certificate Number MDR 718928 </div>

APPROVED BY		
Title: Regulatory Affairs Specialist	Signature: 	Electronically signed by: Champa Patel Reason: I am signing as approver of this document Date: Oct 2, 2024 08:24 GMT+1
Name: Champa Patel	Date: 02-Oct-2024	
Title: Local Quality Manager	Signature: 	Electronically signed by: Melanie Chasse Reason: I am signing as approver of this document Date: Oct 2, 2024 07:08 EDT
Name: Mélanie Chassé	Date: 02-Oct-2024	

On behalf of ArjoHuntleigh AB: Place: Magog










100084270 - 01-Oct-2024

Final Audit Report

2024-10-02

Created:	2024-10-01 (Central European Summer Time)
By:	Joanie Masse (joanie.masse@arjo.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAcgkOHfOYtATeSQf7tkS1ZHJdUiNfVF0u

"100084270 - 01-Oct-2024" History

-  Document created by Joanie Masse (joanie.masse@arjo.com)
2024-10-01 - 8:23:40 PM GMT+2
-  Document emailed to Champa Patel (Champa.Patel@arjo.com) for signature
2024-10-01 - 8:24:23 PM GMT+2
-  Email viewed by Champa Patel (Champa.Patel@arjo.com)
2024-10-02 - 9:23:46 AM GMT+2
-  Champa Patel (Champa.Patel@arjo.com) authenticated with Adobe Acrobat Sign.
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2024-10-02 - 9:24:09 AM GMT+2
-  Document e-signed by Champa Patel (Champa.Patel@arjo.com)
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Signature Date: 2024-10-02 - 9:24:25 AM GMT+2 - Time Source: server
-  Champa Patel (Champa.Patel@arjo.com) authenticated with Adobe Acrobat Sign.
Challenge: The user completed the signing ceremony.
2024-10-02 - 9:24:25 AM GMT+2
-  Document emailed to Melanie Chasse (Melanie.Chasse@arjo.com) for signature
2024-10-02 - 9:24:26 AM GMT+2
-  Melanie Chasse (Melanie.Chasse@arjo.com) authenticated with Adobe Acrobat Sign.
Challenge: The user clicked on the signature field: 'Signature 2'.
2024-10-02 - 1:08:29 PM GMT+2
-  Melanie Chasse (Melanie.Chasse@arjo.com) authenticated with Adobe Acrobat Sign.
Challenge: The user completed the signing ceremony.
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Declaration of Conformity

Manufacturer	ArjoHuntleigh AB Hans Michelsensgatan 10 211 20 Malmö, Sweden
Single Registration Number	SE-MF-000000696
Declaration	ArjoHuntleigh AB as the manufacturer of the following medical devices, takes sole responsibility and declares conformity with the applicable provisions of Medical Device Regulation (EU) 2017/745 concerning medical devices, by Annex IX.
Device Family Name	Sara Flex – HEB2xxx-xx Where x depends of the options and country
Intended Purpose	Mobile Lifter - Patient/Resident
Basic UDI-DI	5060693520082W3
Risk Class and Rule	Class IM, Rule 13
Additional Information	Also complies with the following EU Legislation: Machinery Directive 2006/42/EC RoHS Directive 2011/65/EU as amend Non-Automatic Weighing Instruments Directive 2014/31/EU
Notified Body Name and Number	 BSI Group The Netherlands B.V. Number: 2797 CE Certificate Number MDR 718928

APPROVED BY		
Title: Regulatory Affairs Specialist	Signature: 	Electronically signed by: Champa Patel Reason: I am signing as approver of this document Date: Oct 2, 2024 08:25 GMT+1
Name: Champa Patel	Date: 02-Oct-2024	
Title: Local Quality Manager	Signature: 	Electronically signed by: Melanie Chasse Reason: I am signing as approver of this document Date: Oct 2, 2024 07:07 EDT
Name: Mélanie Chassé	Date: 02-Oct-2024	

On behalf of ArjoHuntleigh AB: Place: Magog










100084271 - 01-Oct-2024

Final Audit Report

2024-10-02

Created:	2024-10-01 (Central European Summer Time)
By:	Joanie Masse (joanie.masse@arjo.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAzY3Ykons1gmcHrrQ7oT-Y02VFwNWJuV1

"100084271 - 01-Oct-2024" History

-  Document created by Joanie Masse (joanie.masse@arjo.com)
2024-10-01 - 8:27:51 PM GMT+2
-  Document emailed to Champa Patel (Champa.Patel@arjo.com) for signature
2024-10-01 - 8:28:34 PM GMT+2
-  Email viewed by Champa Patel (Champa.Patel@arjo.com)
2024-10-02 - 9:24:44 AM GMT+2
-  Champa Patel (Champa.Patel@arjo.com) authenticated with Adobe Acrobat Sign.
Challenge: The user clicked on the signature field: 'Signature 1'.
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-  Champa Patel (Champa.Patel@arjo.com) authenticated with Adobe Acrobat Sign.
Challenge: The user completed the signing ceremony.
2024-10-02 - 9:25:36 AM GMT+2
-  Document e-signed by Champa Patel (Champa.Patel@arjo.com)
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Signature Date: 2024-10-02 - 9:25:37 AM GMT+2 - Time Source: server
-  Document emailed to Melanie Chasse (Melanie.Chasse@arjo.com) for signature
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-  Melanie Chasse (Melanie.Chasse@arjo.com) authenticated with Adobe Acrobat Sign.
Challenge: The user clicked on the signature field: 'Signature 2'.
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-  Melanie Chasse (Melanie.Chasse@arjo.com) authenticated with Adobe Acrobat Sign.
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