

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	Alpha Active 4 -Mattress
Basic UDI-DI	5060693520136
GMDN Number and Term	41900-Alternating –pressure bed mattress overlay,reusable
Additional Information	Also complies with the following EU Legislation: None
Risk Class and Rule	 Class I, Rule 1

APPROVED BY		
Title: Local Quality Manager	Signature:	
Name: Angela Jiang	Date:	26-MAY-2021
Title: Regulatory Compliance Manager	Signature:	
Name: David Moynham	Date:	26-MAY-2021

On behalf of ArjoHuntleigh AB: Place Suzhou.

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Product Model Numbers

Document #	Title
648322	AA4 mattress 90cm wide PVC
648322W	AA4 mattress 90cm wide PVC welded
648324	AA4 mattress 85cm wide PVC
648324W	AA4 mattress 85cm wide PVC welded
648326	AA4 mattress 85cm wide PU
648326W	AA4 mattress 85cm wide PU welded
648333	AA4 mattress 80cm wide PU
648333W	AA4 mattress 80cm wide PU welded
648334	AA4 mattress 90cm wide PU
648334W	AA4 mattress 90cm wide PU welded

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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	Alpha Active 4 Pump 64831x 64831xxx
Intended Purpose	For the prevention and/or management of pressure injuries.
Basic UDI-DI	5060693520020VD
Risk Class and Rule	Class IIa, Rule 9
Additional Information	Also complies with the following EU Legislation: RoHS Directive 2011/65/EU as amended. WEEE Directive 2012/19/EU
Notified Body Name and Number	 BSI Group The Netherlands B.V. Number: 2797 CE Certificate Number MDR 718928

APPROVED BY			
Title: Local Quality Manager		Signature:	
Name: Angela Jiang		Date:	2022-01-07
Title: Sr. Regulatory Compliance Manager		Signature:	
Name: David Moynham		Date:	07-JAN-2022

On behalf of ArjoHuntleigh AB: Place: Suzhou