

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 3 – Mattress
Intended Purpose	For the prevention and/or management of pressure ulcers
Basic UDI-DI	5060693520136VZ
Additional Information	Also complies with the following EU Legislation: None
Risk Class and Rule	Class I, Rule 1

APF	PROVED BY	
Title:Local Quality Manager	Signature: 花戏 Jugele Jarg	Electronically signed by: Angela Jiang Reason: I am signing as approver of this document Date: May 13, 2024 13:18 GMT+8
Name:Angela Jiang	Date:	
Title:Senior Regulatory Compliance Manager	Signature: Mayrlaure	Electronically signed by: david moynham Reason: I am signing as approver of this document Date: May 13, 2024 07:32 GMT+1
Name:David Moynham	Date:	

On behalf of ArjoHuntleigh AB: Place:Suzhou



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Product Model Numbers

Document #	Title
648325	ALPHA ACTIVE 3 OVERLAY 85CM PU
648325W	ALPHA ACTIVE 3 OVERLAY 85CM PU WELDED
648342	ALPHA ACTIVE 3 OVERLAY 80CM PU
648342W	ALPHA ACTIVE 3 OVERLAY 80CM PU WELDED
648343	ALPHA ACTIVE 3 OVERLAY 90CM PU
648343W	ALPHA ACTIVE 3 OVERLAY 90CM PU WELDED