Declaration of Conformity

Manufacturer	**ArjoHuntleigh AB** Hans Michelsensgatan 10 211 20 Malmö, Sweden
Single Registration Number	Not available at date of signing
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
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	CE Class I, Rule 1

APPROVED BY		
Title: Local Quality Manager	Signature:	Angela Jiang
Name: Angela Jiang	Date:	2019-12-06
Title: Regulatory Compliance Manager	Signature:	D. Moynham
Name: David Moynham	Date:	2019 DEC 06

On behalf of ArjoHuntleigh AB: Place Suzhou.

Form: SOP-047-B rev.5

Declaration of Conformity

Product Model Numbers

Document #	Title
648321	ALPHA ACTIVE 3 OVERLAY 90CM
648321W	ALPHA ACTIVE 3 OVERLAY 90CM WELDED
648323	ALPHA ACTIVE 3 OVERLAY 85CM
648323W	ALPHA ACTIVE 3 OVERLAY 85CM WELDED
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

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	Alpha Active 3 Pump 64830x 64830xxx
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	CE 2797 BSI Group The Netherlands B.V. Number: 2797 CE Certificate Number MDR 718928

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

On behalf of ArjoHuntleigh AB: Place: Suzhou

Form: SOP-047-C rev.6