
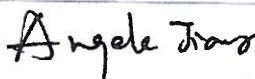
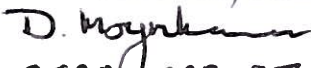



Declaration of Conformity



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 5 –Mattress 648202 648203
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: 2020-06-07
Title: Regulatory Compliance Manager	Signature: 
Name: David Moynham	Date: 2020 APR-07

On behalf of ArjoHuntleigh AB: Place: Suzhou.

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 5 Pump 64820x 64820xx
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	 2797 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