



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	AtmosAir Velaris Mattresses, ST Mattresses & Seat Cushions (Part numbers & additional details on next page).
Intended Purpose	For the prevention and/or management of pressure injuries.
Basic UDI-DI	5060693520174W9
Additional Information	Also complies with the following EU Legislation: Nil
Risk Class and Rule	 Class I, Rule 1


APPROVED BY	
Title: Regulatory Affairs Specialist	Signature: 
Name: Champa Patel	Date: 12-Dec-2023

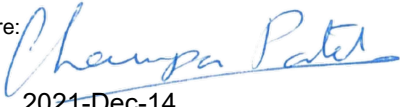
On behalf of ArjoHuntleigh AB: Place: Cardiff

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Part Number	Size: mm (inches)	Top Cover
Standard Mattress		
633048	810 x 2000 x 180 (32 x 79 x 7)	Reliant
633049	810 x 2000 x 180 (32 x 79 x 7)	Premium
633020	860 x 1980 x 180 (34 x 78 x 7)	Reliant
633026	860 x 1980 x 180 (34 x 78 x 7)	Premium
633021	880 x 2020 x 180 (35 x 80 x 7)	Reliant
633027	880 x 2020 x 180 (35 x 80 x 7)	Premium
633022	880 x 2140 x 180 (35 x 84 x 7)	Reliant
633028	880 x 2140 x 180 (35 x 84 x 7)	Premium
633023	900 x 2000 x 180 (35 x 79 x 7)	Reliant
633029	900 x 2000 x 180 (35 x 79 x 7)	Premium
633900	1060 X 1980 X 180 (42 X 78 X 7)	Reliant
633901	1060 X 1980 X 180 (42 X 78 X 7)	Premium
633024	1070 x 2000 x 180 (42 x 79 x 7)	Reliant
633030	1070 x 2000 x 180 (42 x 79 x 7)	Premium
PLUS Mattress		
633025	1220 x 2140 x 180 (48 x 84 x 7)	Reliant
633031	1220 x 2140 x 180 (48 x 84 x 7)	Premium
PLUS-Flex Mattress with bolsters		
633902	1220 x 2240 x 180 (48 x 88 x 7)	Reliant
633903	1220 x 2240 x 180 (48 x 88 x 7)	Premium
ST Mattress		
633042	670 x 1950 x 130 (26 x 77 x 5)	Reliant
633043	670 x 1950 x 130 (26 x 77 x 5)	Premium
633044	660 x 1910 x 130 (26 x 75 x 5)	Reliant
633045	660 x 1910 x 130 (26 x 75 x 5)	Premium
633046	762 x 1910 x 130 (30 x 75 x 5)	Reliant
633047	762 x 1910 x 130 (30 x 75 x 5)	Premium
Seat Cushion		
633016	432 x 432 x 100 (17 x 17 x 4)	Reliant
633018	432 x 432 x 100 (17 x 17 x 4)	Premium
633017	457 x 457 x 100 (18 x 18 x 4)	Reliant
633019	457 x 457 x 100 (18 x 18 x 4)	Premium

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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	AtmosAir Velaris Pump 6330xx
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 2797 CE Certificate Number MDR 718928

APPROVED BY	
Title: Regulatory Affairs Specialist	Signature: 
Name: Champa Patel	Date: 2021-Dec-14

On behalf of ArjoHuntleigh AB: Place: Cardiff