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	Auralis Mattress & Seat Cushion
Intended Purpose	For the prevention and/or management of pressure injuries
Basic UDI-DI	5060693520136VZ
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:	1st -Nov -2022
Title:Senior Regulatory Compliance Manager	Signature:	D. Moynham
Name:David Moynham	Date:	01-NOV-2022

On behalf of ArjoHuntleigh AB: Place: Suzhou

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Declaration of Conformity

Product/Model Numbers	Description
636T01S	Auralis Mattress Standard 110
636T01N	Auralis Mattress Narrow 110
636M02S	Auralis Mattress Standard 200
636M02N	Auralis Mattress Narrow 200
636M05S 636M05SUS 636M05SCA	Auralis Mattress Standard 175 US labelled variant CA labelled variant
636M05N 636M05NUS 636M05NCA	Auralis Mattress Narrow 175 US labelled variant CA labelled variant
636B02	Auralis Plus Mattress
636C01S	Auralis Seat Cushion
636T01S-P	Auralis 110 mattress STD
636T01N-P	Auralis 110 mattress NAR
636M05S-P	Auralis 175 mattress STD
636M05N-P	Auralis 175 mattress NAR
636M02S-P	Auralis 200 mattress STD
636M02N-P	Auralis 200 mattress NAR
636B02-P	Auralis Plus Mattress

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	Auralis Pump 6360xx 6360xxxx 636003US-P
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 amend [Delete if not applicable] WEEE Directive 2012/19/EU [Delete if not applicable]
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:	1st -Nov-2022
Title:Senior Regulatory Compliance Manager	Signature:	D. Moynham
Name:David Moynham	Date:	01-NOV-2022

On behalf of ArjoHuntleigh AB: Place: Suzhou

Form: SOP-047-C rev.6