

## Declaration of Conformity

|                            |                                                                                                                                                                                                                                |
|----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Manufacturer               | <b>ArjoHuntleigh AB</b><br>Hans Michelsensgatan 10<br>211 20 Malmö, Sweden                                                                                                                                                     |
| Single Registration Number | <b>SE-MF-000000696</b>                                                                                                                                                                                                         |
| 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:<br>None.                                                                                                                                                                      |
| Risk Class and Rule        |  Class I, Rule 1                                                                                                                            |

| APPROVED BY                                |                                                                                                  |
|--------------------------------------------|--------------------------------------------------------------------------------------------------|
| Title:Local Quality Manager                | Signature:  |
| Name: Angela Jiang                         | Date: 1st Nov 2022                                                                               |
| Title:Senior Regulatory Compliance Manager | Signature:  |
| Name:David Moynham                         | Date: 01-NOV 2022                                                                                |

On behalf of ArjoHuntleigh AB: Place: Suzhou

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| 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               | Auralis Mattress Standard 175 |
| 636M05SUS             | US labelled variant           |
| 636M05SCA             | CA labelled variant           |
| 636M05N               | Auralis Mattress Narrow 175   |
| 636M05NUS             | US labelled variant           |
| 636M05NCA             | 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         |