



## 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         | 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 |
|---|---------------------------------|-----------|
| <b>Standard Mattress</b>                |                                 |           |
| 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   |
| <b>PLUS Mattress</b>                    |                                 |           |
| 633025                                  | 1220 x 2140 x 180 (48 x 84 x 7) | Reliant   |
| 633031                                  | 1220 x 2140 x 180 (48 x 84 x 7) | Premium   |
| <b>PLUS-Flex Mattress with bolsters</b> |                                 |           |
| 633902                                  | 1220 x 2240 x 180 (48 x 88 x 7) | Reliant   |
| 633903                                  | 1220 x 2240 x 180 (48 x 88 x 7) | Premium   |
| <b>ST Mattress</b>                      |                                 |           |
| 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   |
| <b>Seat Cushion</b>                     |                                 |           |
| 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   |