
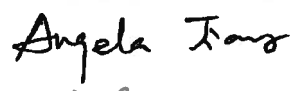
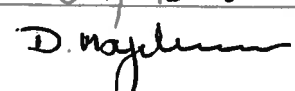


Declaration of Conformity

| | |
|----------------------------|--|
| 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 3 -Mattress |
| 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: | 2019-12-06 | |
| Title: Regulatory Compliance Manager | Signature: |  | |
| Name: David Moynham | Date: | 2019 DEC 06 | |


On behalf of ArjoHuntleigh AB: Place Suzhou.

Declaration of Conformity

Product Model Numbers

| Document # | Title |
|------------|---------------------------------------|
| 648321 | ALPHA ACTIVE 3 OVERLAY 90CM |
| 648321W | ALPHA ACTIVE 3 OVERLAY 90CM WELDED |
| 648323 | ALPHA ACTIVE 3 OVERLAY 85CM |
| 648323W | ALPHA ACTIVE 3 OVERLAY 85CM WELDED |
| 648325 | ALPHA ACTIVE 3 OVERLAY 85CM PU |
| 648325W | ALPHA ACTIVE 3 OVERLAY 85CM PU WELDED |
| 648342 | ALPHA ACTIVE 3 OVERLAY 80CM PU |
| 648342W | ALPHA ACTIVE 3 OVERLAY 80CM PU WELDED |
| 648343 | ALPHA ACTIVE 3 OVERLAY 90CM PU |
| 648343W | ALPHA ACTIVE 3 OVERLAY 90CM PU WELDED |

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 3 Pump 64830x 64830xxx |
| 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: <i>Angela Jiang</i> |
| Name: Angela Jiang | Date: <i>2022-01-07</i> |
| Title: Sr. Regulatory Compliance Manager | Signature: <i>D. Moynham</i> |
| Name: David Moynham | Date: <i>07-JAN-2022</i> |

On behalf of ArjoHuntleigh AB: Place: Suzhou