



# Manufacturer's Declaration of Conformity

Australian Therapeutic Goods (Medical Devices) Regulations 2002

This is a declaration made in accordance with the requirements of Clause 1.8 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002, relating to the stated devices.

Manufacturer Name and Address	<b>ArjoHuntleigh AB</b> Hans Michelsensgatan 10 211 20 Malmö, Sweden
Medical Device(s)	<b>Airpal disposable transfer mattresses:</b> <ul style="list-style-type: none"> <li>• AP-028SPSLH</li> <li>• AP-034SPS</li> <li>• AP-039SPS</li> <li>• AP-050SPS</li> <li>• AP-034SPSH</li> <li>• AP-039SPSH</li> </ul>
Classification	Class I
GMDN Code and Term	<b>37163 - Patient transfer sliding mat</b>
Declaration	Each kind of medical device complies with the applicable provisions of the essential principles and the classification rules before being supplied.
Scope of Application	All serial numbers to which the Declaration of Conformity (not requiring assessment by the Secretary) Procedure has been applied.
Production Quality Management System Certificate	British Standards Institute (BSI) BSI EN ISO 13485:2016 Certificate #MD87841
Standards Applied	EN ISO 13485:2016 EN ISO 14971:2019 ISO 10993-1:2018 ISO 15223-1:2021

APPROVED BY		
Title: Regulatory Affairs Specialist	Signature: 	<i>Electronically signed by: Champa Patel Reason: I am signing as approver of this document Date: Jun 19, 2023 09:40 GMT+1</i>
Name: Champa Patel	Date: 19-Jun-2023	
Title: Local Quality Manager	Signature: 	<i>Electronically signed by: yacaida almonte Reason: I am signing as approver of this document Date: Jun 15, 2023 15:25 EDT</i>
Name: Yacaida Almonte	Date: 15-Jun-2023	