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	**ArjoHuntleigh AB** Hans Michelsensgatan 10 211 20 Malmö, Sweden
Medical Device(s)	**SARA STEDY** **SARA STEDY COMPACT**
Classification	Class I
GMDN Code and Term	**12329, Lift**
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 10535:2006

APPROVED BY	
Title: Regulatory Affairs Specialist	Signature: Champa Patel
Name: Champa Patel	Date: 2022-MAR-16
Title: Local Quality Manager	Signature:
Name: Mélanie Chassé	Date: 16-Mar-2022

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