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	**Citadel Plus Bariatric Care System** FXxxxxxxxxxxx
Intended Purpose	Medical Bed
Basic UDI-DI	**5060693520075W6**
Risk Class and Rule	Class IM, Rule 13 + metrology function
Additional Information	Also complies with the following EU Legislation: Machinery Regulation (EU) 2023/1230 RoHS Directive 2011/65/EU as amend Non-Automatic Weighing Instruments Directive 2014/31/EU
Notified Body Name and Number	CE 2797 BSI Group The Netherlands B.V. Number: 2797 CE Certificate Number MDR 718928

APPROVED BY			
Title: Local Quality Manager	Signature:	Nowotna Anna	*Electronically signed by: Anna Nowotna Reason: I am signing as approver of this document Date: Nov 12, 2024 11:47 GMT+1*
Name: Anna Nowotna	Date:	12-Nov-2024	
Title: Senior Regulatory Compliance Manager	Signature:	D. Moynham	*Electronically signed by: david moynham Reason: I am signing as approver of this document Date: Nov 14, 2024 14:37 GMT*
Name: David Moynham	Date:	14-Nov-2024	

On behalf of ArjoHuntleigh AB: Place: Poznan

Form: SOP-047-C rev.6