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.
Device Family Name	Sara Plus Active Slings: Models: **KKA5120, KKA5370, KKA5130M, KKA5420, MFA4000**
Intended Purpose	Patient/Resident – Non-Rigid support for Lifters
Basic UDI-DI	5060693520150VT
Additional Information	Also complies with the following EU Legislation: Machinery Regulation 2023/1230/EU
Risk Class and Rule	CE Class I, Rule 1

APPROVED BY		
Title: Local Quality Manager	Signature: Yacaida Almonte	*Electronically signed by: yacaida almonte Reason: I am signing as Approver of this document Date: Feb 11, 2025 09:18 AST*
Name: yacaida almonte	Date: 11-Feb-2025	
Title: Snr Regulatory Compliance Manager	Signature: D. Moynham	*Electronically signed by: david moynham Reason: I am signing as Approver of this document Date: Feb 11, 2025 13:25 GMT*
Name: david moynham	Date: 11-Feb-2025	

On behalf of ArjoHuntleigh AB: Place: Dominican Republic

Form: SOP-047-B rev.7