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 3000 / Lite / Stedy / Flex Active Sling Models: • TSS.500 • TSS.501 • TSS.502 • TSS.503 • TSS.504 • TSS.501A • TSS.502A • TSS.503A • TSS.500S-1C • TSS.501S-1C • TSS.502S-1C • TSS.503S-1C • TSS.501SV • TSS.502SV • TSS.511 • MAA3060M • MAA3061M • MAA3070M • MAA3071M • MFA3000
Intended Purpose	Patient/Resident - Non-Rigid support for Lifters
Basic UDI-DI	**5060693520150VT**
Additional Information	Also complies with the following EU Legislation: Machinery Directive 2006/42/EC
Risk Class and Rule	CE Class I, Rule 1

APPROVED BY	
Title: Senior Regulatory Compliance Manager	Signature: D. Moynham
Name: David Moynham	Date: 31-Jan-2022
Title: Local Quality Manager	Signature: Yacaida Almonte
Name: Yacaida Almonte	Date: 28/Jan/2022

On behalf of ArjoHuntleigh AB: Place: Dominican Replublic

Form: SOP-047-B rev.6