

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	MP1/MP1R		
Intended Purpose	It is a diagnostic device intended to allow direct diagnosis or monitoring of vital physiological processes.		
Basic UDI-DI	5060693520372WF		
Risk Class and Rule	Class IIb, Rule 10		
Additional Information	Manufactured and distributed on behalf of ArjoHuntleigh AB by: Huntleigh Healthcare Ltd 35 Portmanmoor Road Cardiff CF24 5HN United Kingdom Also complies with the following EU Legislation: RoHS Directive 2011/65/EU WEEE Directive 2012/19/EU		
Notified Body Name and Number	BSI Group The Netherlands B.V. Number: 2797 CE Certificate Number MDR 718928		

	APPROVED BY	
Title: QRE Compliance Director	Signature:	V.m.
Name: Steve Monks	Date:	19/12/2023

On behalf of ArjoHuntleigh AB: Place: Cardiff