



# Declaration of Conformity

Manufacturer	<b>ArjoHuntleigh AB</b> Hans Michelsensgatan 10 211 20 Malmö, Sweden
Single Registration Number	<b>SE-MF-000000696</b>
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	<b>TEAM3 Antepartum</b> see Appendix for list of variants
Intended Purpose	The product is intended to monitor fetal heart and vital signs of pregnant woman.
Basic UDI-DI	5060693520389WY
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	 <b>2797</b> BSI Group The Netherlands B.V. Number: 2797 CE Certificate Number MDR 718928

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

On behalf of ArjoHuntleigh AB: Place: Cardiff

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### Appendix

TEAM3A		ANTEPARTUM/PRINTER
TEAM3A	3	ANTEPARTUM/PRINTER-TRIPLETS
TEAM3A	B	ANTEPARTUM/PRINTER+BATTERY
TEAM3A	E	ANTEPARTUM/ECTG
TEAM3A	N	ANTEPARTUM/PRINTER+NIBP
TEAM3A	S	ANTEPARTUM/PRINTER+SPO2
TEAM3A	B3	ANTEPARTUM/PRT+BATTERY-TRIPLETS
TEAM3A	E3	ANTEPARTUM/ECTG-TRIPLETS
TEAM3A	EB	ANTEPARTUM/ECTG+BAT
TEAM3A	ENS	TEAM3 ANTEPARTUM +NIBP + SPO2,NO PRINTER
TEAM3A	N3	ANTEPARTUM/PRT+NIBP-TRIPLETS
TEAM3A	NB	ANTEPARTUM/PRINTER+NIBP+BAT
TEAM3A	NS	ANTEPARTUM/PRINTER+NIBP+SPO2
TEAM3A	S3	ANTEPARTUM/PRINTER+SPO2-TRIPLETS
TEAM3A	SB	ANTEPARTUM/PRINTER+SPO2+BAT
TEAM3A	EB3	ANTEPARTUM/ECTG+BAT-TRIPLETS
TEAM3A	NB3	ANTEPARTUM/PRT+NIBP+BAT-TRIPLETS
TEAM3A	NS3	ANTEPARTUM/PRT+NIBP+SPO2-TRIPLETS
TEAM3A	NSB	ANTEPARTUM/PRINTER+NIBP+SPO2+BAT
TEAM3A	SB3	ANTEPARTUM/PRT+SPO2+BAT-TRIPLETS
TEAM3A	ENSB	TEAM3 ANTEPARTUM +NIBP + SPO2 + BATTERY,NO PRINTER
TEAM3A	NSB3	ANTEPARTUM/PRT+NIBP+SPO2+BAT-TRIP
TEAM3A	ECTG	ANTEPARTUM/ECTG+BAT
TEAM3G1	ECTG	ANTEPARTUM/ECTG/BASIC/SINGL
TEAM3G2		TEAM 3A BASIC
TEAM3G2	ECTG	TEAM 3A ECG BASIC
TEAM3A	ENM	ANTE/ECTG+NIBP+SPO2NEL
TEAM3A	NM	ANTE/PRINT+NIBP+SPO2NEL
TEAM3A	NM3	ANTE/PRINT+SPO2NEL-TRIP
TEAM3A	NMB	ANTE/PRINT+NIBP+SPO2NEL+BAT
TEAM3A	NMB3	ANTE/PRINT+NIBP+SPO2NEL+BAT-TRIP
TEAM3A	M	ANTE/PRINT+SPO2NEL
TEAM3A	MB	ANTE/PRINT+SPO2NEL+BAT