



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	TEAM3 Intrapartum 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	 2797 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

TEAM3I		INTRAPARTUM/PRINTER
TEAM3I	3	INTRAPARTUM/PRINTER-TRIPLETS
TEAM3I	B	INTRAPARTUM/PRINTER+BATTERY
TEAM3I	N	INTRAPARTUM/PRINTER+NIBP
TEAM3I	S	INTRAPARTUM/PRINTER+SPO2
TEAM3I	B3	INTRAPARTUM/PRINTER+BAT-TRIPLETS
TEAM3I	N3	INTRAPARTUM/PRINTER+NIBP-TRIPLETS
TEAM3I	NB	INTRAPARTUM/PRINTER+NIBP+BATTERY
TEAM3I	NS	INTRAPARTUM/PRINTER+NIBP+SPO2
TEAM3I	S3	INTRAPARTUM/PRINTER+SPO2-TRIPLETS
TEAM3I	SB	INTRAPARTUM/PRINTER+SPO2+BATTERY
TEAM3I	NB3	INTRAPARTUM/PRT+NIBP+BAT-TRIPLETS
TEAM3I	NS3	INTRAPARTUM/PRT+NIBP+SPO2-TRIPLET
TEAM3I	NSB	INTRAPARTUM/PRINTER+NIBP+SPO2+BATTERY
TEAM3I	SB3	INTRAPARTUM/PRT+SPO2+BAT-TRIPLETS
TEAM3I	NSB3	INTRAPARTUM/PRT+NIBP+SOP2+BAT-TRI
TEAM3I	NM	INTRA/PRINT+NIBP+SPO2NEL
TEAM3I	NM3	SP-777232 ANALOGUE SCREEN PCB
TEAM3I	NMB	INTRA/PRINT+NIBP+SPO2NEL+BAT
TEAM3I	NMB3	INTRA/PRINT+NIBP+SPO2NEL+BAT-TRIP
TEAM3I	M	INTRA/PRINT+SPO2NEL
TEAM3I	MB	INTRA/PRINT+SPO2NEL+BAT
TEAM3I	E	TEAM3 INTRAPARTUM/ECTG
TEAM3I	E3	TEAM3/ECTG-TRIPLETS
TEAM3I	EB3	TEAM3/ECTG+BAT-TRIPLETS
TEAM3I	ENSB	TEAM3 INTRAPARTUM/ECTG+NIBP+SPO2+BAT