


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	Toco Transducer (ACC-OBS-009, ACC-OBS-009L)
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 IIa, 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: 
Name: Steve Monks	Date: 19/12/2023

On behalf of ArjoHuntleigh AB: Place: Cardiff