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	High Sensitivity obstetric probe (OP2XS, OP3XS)
Intended Purpose	The product is intended to monitor fetal heart rate.
Basic UDI-DI	5060693520358WM
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	CE 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

Form: SOP-047-C rev.6