Declaration of Conformity

Manufacturer	**ArjoHuntleigh AB** Hans Michelsensgatan 10 211 20 Malmö, Sweden
Declaration	ArjoHuntleigh AB as the manufacturer of the following medical devices, declare conformity with the applicable provisions of Directive 93/42/EEC of 14 June 1993, concerning medical devices, by Annex II.
Additional information	Manufactured and distributed on behalf of ArjoHuntleigh AB by: Huntleigh Healthcare Ltd 35 Portmanmoor Road Cardiff CF24 5HN United Kingdom
Device Family Name	Handheld Fetal Monitor – D920 / D930 / FD1 / FD2 / FD3
GMDN Number and Term	34040 **Fetal Doppler system**
Risk Class and Rule	Class IIa, Rule 10
Notified Body Name and Number	CE 2797 BSI 2797 CE Certificate Number CE01945

APPROVED BY	
Title: QRE Compliance Director	Signature:
Name: Steve Monks	Date: 08/02/2021

Form: SOP-047-C rev.5