


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	Sonicaid Freedom (SF1-EUR)
GMDN Number and Term	38479 Cardiotocography telemetric monitoring system
Risk Class and Rule	Class IIb, Rule 10
Notified Body Name and Number	 BSI 2797 2797 CE Certificate Number CE01945

APPROVED BY	
Title: QRE Compliance Director	Signature: 
Name: Steve Monks	Date: 7 th December 2020