


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.
Device Family Name	Reusable Transducer Belt (Fetal Monitor Accessory) – ACC-MI1136
Basic UDI-DI	05051968032713
GMDN Number and Term	37685 Personal Device Holder, Reusable
Additional Information	Manufactured and distributed on behalf of ArjoHuntleigh AB by: Huntleigh Healthcare Ltd 35 Portmanmoor Road Cardiff CF24 5HN United Kingdom
Risk Class and Rule	 Class I, Rule 1

APPROVED BY	
Title: QRE Compliance Director	Signature: 
Name: Steve Monks	Date: 17/11/2021

On behalf of ArjoHuntleigh AB: Place: Cardiff