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	DMX, DMXR
Intended Purpose	The Doppler is indicated for the assessment of blood flow, within veins and arteries, by audible and visual means.
Basic UDI-DI	5060693520365WJ
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