

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	Hand Held Vascular Blood Flow Monitor – DMX/DMXR Vascular Doppler Probe – EZ8XS, VP5XS (Ankle Brachial Index Measurement – ABI)	
GMDN Number and Term	44311 Non-invasive vascular ultrasound system	
Risk Class and Rule	Class IIa, Rule 10	
Notified Body Name and Number	BSI 2797 CE Certificate Number CE01945	

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