


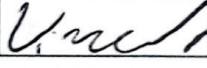
(PROJECT NUMBER HD771)
(DOPPLEX ABILITY)

Declaration of Conformity Class IIa

Author:

Name	Title	Sign	Date
Betina Bandojo	Regulatory Compliance Engineer		13-JAN-2022

Approver:

Name	Title	Sign	Date
Steve Monks	QRE Compliance Director		13/01/2022

Issue History

Issue No	Date	Description of change
1	14-DEC-2021	Transfer to new template

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.
Device Family Name	Dopplex Ability – see Appendix I for list of configurations/variants
GMDN Number and Term	58928 Noninvasive ankle brachial pressure index measurement unit
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
Notified Body Name and Number	CE 2797 BSI 2797 CE Certificate Number CE01945

APPROVED BY	
Title: QRE Compliance Director	Signature: 
Name: Steve Monks	Date: 13/01/2022

Appendix I

DA100	ABILITY WITHOUT BATTERY + PRINTER
DA100B	ABILITY WITH BATTERY
DA100P	ABILITY WITH PRINTER
DA100PB	ABILITY WITH PRINTER + BATTERY