HUNTLEIGH

A MEMBER OF THE ARJO FAMILY

(PROJECT NUMBER HD771)

(DOPPLEX ABILITY)

Declaration of Conformity Class IIa

Author:

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

Approver:

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

Issue History

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

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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

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Appendix I

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