arjo

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	**SC500** see Appendix for list of variants
Intended Purpose	It is a diagnostic device intended to allow direct diagnosis or monitoring of vital physiological processes.
Basic UDI-DI	5060693520372WF
Risk Class and Rule	Class IIb, 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: V. Monks
Name: Steve Monks	Date: 19/12/2023

On behalf of ArjoHuntleigh AB: Place: Cardiff

Form: SOP-047-C rev.6

Appendix

SC500	H	SC500 BASIC MONITOR
SC500	N	SC500 NELLCOR
SC500	HE	SC500 BASIC + ECG
SC500	HP	SC500 BASIC + PRINTER
SC500	HT	SC500 BASIC + TEMP
SC500	NE	SC500 NELLCOR + ECG
SC500	NP	SC500 NELLCOR + PRINTER
SC500	NT	SC500 NELLCOR + TEMP
SC500	HEP	SC500 BASIC + ECG + PRINTER
SC500	HTE	SC500 BASIC + TEMP + ECG
SC500	HTP	SC500 BASIC + TEMP + PRINTER
SC500	NEP	SC500 NELLCOR + ECG + PRINTER
SC500	NTE	SC500 NELLCOR + TEMP + ECG
SC500	NTP	SC500 NELLCOR + TEMP + PRINTER
SC500	HTEP	SC500 BASIC + TEMP +ECG+PRINTER
SC500	NTEP	SC500 NELLCOR + TEMP +ECG+PRINTER