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	Intermittent Pneumatic Compression – HYDROVEN 3 PUMP: 510001, 510003, 510003US, 510EUR, 510009AU, 510STD, 510004DK HYDROVEN 12 Lymphassist Homecare Pump: 316EURHC HYDROVEN 12 PUMP: 316001, 316003, 316EUR, 316004DE, 316009AU, 316004DK
GMDN Number and Term	16837 **Sequential Venous Compression System**
Basic UDI-DI	**5060693520013**
Risk Class and Rule	Class IIa, Rule 9
Additional Information	Also complies with the following EU Legislation: RoHS Directive 2011/65/EU WEEE Directive 2012/19/EU 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 MDR 718928

Form: SOP-047-C rev.5

Declaration of Conformity

APPROVED BY	
Title: QRE Compliance Director	Signature:
Name: Steve Monks	Date: 25/03/2022

On behalf of ArjoHuntleigh AB: Place: Cardiff