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 1 GARMENTS: 5101L50, 5101L66, 5101L71, 5101L76, 5101L84, 5101L92, 5101A51, 5101A68, 5101A78
GMDN Number and Term	30877 **Single-chamber venous compression system garment, reusable**
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

APPROVED BY	
Title: QRE Compliance Director	Signature:
Name: Steve Monks	Date: 17/06/21

On behalf of ArjoHuntleigh AB: Place: Cardiff

Form: SOP-047-C rev.5