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 – <u>HYDROVEN 3 GARMENTS:</u> 5103A68, 5103A78, 5103L50, 5103L66, 5103L71, 5103L76, 5103L84, 5103L92, 510AI68, 510AI78, 510LI50, 510LI66, 510LI71, 510LI76, 510LI84, 510LI92 <u>HYDROVEN 12 GARMENTS:</u> 316L76S, 316L84S, 316L76W, 316L84W, 316A68, 316A78 316LI76, 316LI84, 316AI68, 316AI78, 316T78, 316J78
GMDN Number and Term	44768 **Multi-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: 31st August 2022

On behalf of ArjoHuntleigh AB: Place: Cardiff

Form: SOP-047-C rev.5