




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.
Device Family Name	PENTAFLEX (refer to Attachment 1 for parts numbers)
Intended Purpose	For the prevention and/or management of pressure injuries.
Basic UDI-DI	5060693520174W9
Additional Information	Also complies with the following EU Legislation: Nil
Risk Class and Rule	 Class I, Rule 1

APPROVED BY		
Title: Local Quality Manager	Signature: 	<i>Electronically signed by: Anna Nowotna Reason: I am signing as approver of this document Date: Apr 19, 2024 16:08 GMT+2</i>
Name: Anna Nowotna	Date:	
Title: Senior Regulatory Affairs Specialist	Signature: 	<i>Electronically signed by: Champa Patel Reason: I am signing as approver of this document Date: Apr 19, 2024 08:17 GMT+1</i>
Name: Champa Patel	Date:	

On behalf of ArjoHuntleigh AB: Place: Poznan

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Attachment 1

Device number / code	MR*/ SEAT	Description
150SL000/000	MR	Pentaflex 2-Way 150kg
250SL000/000	MR	Pentaflex 2-Way 250kg
120PM000/000	MR	Pentaflex 4-Way 120kg
250PM000/000	MR	Pentaflex 4-Way 250kg
25PM000/000	MR	Paediatric Pentaflex
PMSB000/000	MR	Mattress Pentaflex Super Baltimore
150SLX000/000	MR	Pentaflex 2-Way 150kg Premium (Welded)
250SLX000/000	MR	Pentaflex 2-Way 250kg Premium (Welded)
120PMX000/000	MR	Pentaflex 4-Way 120kg Premium (Welded)
250PMX000/000	MR	Pentaflex 4-Way 250kg Premium (Welded)
450PM000/000	MR	Pentaflex Plus
PE000/000	MR	Pentaflex Elegance
PS000/000	SEAT	Pentaflex Seat Cushion
150SL000000W	MR	Pentaflex 2-Way 150kg (Welded)
250SL000000W	MR	Pentaflex 2-Way 250kg (Welded)
150SL000000P	MR	Pentaflex 2-Way 150kg (Premium)
250SL000000P	MR	Pentaflex 2-Way 250kg (Premium)
150SL000/000XX**	MR	Pentaflex 2-Way 150kg
250SL000/000XX**	MR	Pentaflex 2-Way 250kg
120PM000/000XX**	MR	Pentaflex 4-Way 120kg
250PM000/000XX**	MR	Pentaflex 4-Way 250kg
PE000/000XX**	MR	Pentaflex Elegance 4-way 140 kg

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PE000/000Hz***	MR	Pentaflex Elegance 4-way 140 kg (with handles)
150SL000/000Hz***	MR	Pentaflex 2-Way 150kg (with handles)
250SL000/000Hz***	MR	Pentaflex 2-Way 250kg (with handles)
120PM000/000Hz***	MR	Pentaflex 4-Way 120kg (with handles)
250PM000/000Hz***	MR	Pentaflex 4-Way 250kg (with handles)
450PM000/000Hz***	MR	Pentaflex Plus (with handles)

*MR — Mattress Replacement

000/000 - length/width

**XX – country code

***Hz – number of handles (H2, H4)