

# Certificate of Registration



**Certificate No.** CE/GBR/2019/08/19

**Issued To:** **Jobskin Ltd**  
13a Harrington Mill  
Leopold Street  
Long Eaton  
Nottingham, NG10 4QG  
UK

**Legal Manufacturer [SRN: Not yet available]**

**Issued By:** **Advena Limited**  
Tower Business Centre, 2nd Flr, Tower  
Street, Swatar, BKR 4013. Malta.

**EC-REP [SRN: MT-AR-00000234]**

**EU Competent Authority:** **Malta Medicines Authority (MMA)**  
Sir Temi Zammit Buildings, Malta Life  
Sciences Park, San Gwann SGN 3000  
Malta.  
Tel: +356 2343 9000  
Email: info.medicinesauthority@gov.mt

We hereby declare that:

- Device registrations for the medical devices mentioned within this certificate have duly been completed with an EU Competent Authority.
- Due to the 26<sup>th</sup> May 2021 Date of Application of Regulation (EU) 2017/745 (MDR) the validity of this certificate is subject to the Legal Manufacturer providing satisfactory evidence that any device claiming compliance to Directive 93/42/EEC (MDD) through Article 120 (3) of Regulation (EU) 2017/745 is legitimately permitted.
- Due to the 26<sup>th</sup> May 2022 Date of Application of Regulation (EU) 2017/746 (IVDR) the validity of this certificate is subject to the Legal Manufacturer providing satisfactory evidence that any device claiming compliance to Directive 98/79/EC (IVDD) through Article 110(3) of Regulation (EU) 2017/746 is legitimately permitted.

Anthony Kirby – Managing Director (Malta)

**Date of Issue:** 26 October 2021

**AR Cover Begins:** 01 November 2021

**AR Cover Ends:** 31 October 2022

This certificate is subject to the organisation maintaining their documentation in compliance with the EU legislation as indicated in this certificate.

This certificate is for the exclusive use of Advena Ltd's clients and is provided pursuant of the European Authorised Representative agreement (Mandate) between Advena Ltd and the client. Advena's responsibility and liability is limited to the terms and conditions of this agreement. Advena Ltd assumes no liability to any party for any loss, expense or damage occasioned by the use of this certificate and the European Authorised Representative agreement (Mandate). Only the client is authorised to copy or distribute this certificate. Any use of the Advena Ltd name by others who are not covered by the above agreement, or any similar contract, is prohibited. This certificate remains valid until the expiry date has been reached or has been terminated by Advena Limited.

# Appendix A



Product Details, Names or Trade Names	EU Legislation	Classification	Device Registration Reference(s)
Body Allure™ Liposuction and Shapewear MTM and RTW Range	MDR	Class I	MT-MDF03-AA260A
Corsets MTM and RTW Orthosis & Gaiters MTM & RTW Orthosis	MDR	Class I	MT-MDF03-AA260B
Premium™ Lymphoedema and Alleviant™ Garment Ranges	MDR	Class I	MT-MDF03-AA260C
Orthowrap™ Orthopaedic MTM and RTW Orthosis/ Supports	MDR	Class I	MT-MDF03-AA260D
Premium, Classic, Interim and Post-Surgical Compression Garments	MDR	Class I	MT-MDF03-AA260E
SDO Sensory Dynamic Orthosis	MDR	Class I	MT-MDF03-AA260F



## Declaration of Conformity

### For Compression Garments for Therapy Management

#### Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Premium, Classic, Interim and Post-Surgical Compression Garments
Legal Manufacturer: (Name on Label)	Medigarments Ltd, 13a Harrington Mill, Leopold Street, Long Eaton, Nottingham, NG10 4QG United Kingdom
Manufacturers SRN:	Not yet available
Basic UDI-DI:	506059893TF20006F
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	The purpose of the Premium, Premium Interim and Classic Pressure garments is to manage problem scars. The garment provides a compression on areas of raised hypertrophic scarring to flatten, soften and reduce scarring and erythema of the scar and aid the natural scar maturation process.
MDR Classification:	Class 1 [Rule 1]
Notified Body:	Not applicable
EC Certificate:	Not applicable
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745.

#### Declaration Signature:

Date: 4th May 2022  
Location: As above  
Name: Debra Wright  
Position: Product Manager



Signed:

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

## Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN ISO 20417:2021	Medical devices. Information supplied by the manufacturer
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2016	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
EN ISO 10993-1:2018 and applicable parts of the EN ISO 10993 series	Biological evaluation of medical devices – Part 1 Evaluation and testing within a risk management process
MEDDEV 2.7-1 rev 4, June 2016	Guidelines on a Medical Devices Clinical Evaluation: A guide for manufacturers and notified bodies
MEDDEV 2.12-1 rev 8, December 2013	Guidelines on a Medical Device Vigilance System.

## Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/NameA1:A143
<b>Premium MTM Garments</b>	
<b>Head &amp; Neck</b>	
111158	Open Face Mask
110540	Face Mask
110550	Chin Strap
110549	Modified Chin Strap
110545	Chin Extension Collar
110017	Head Band
<b>Hand</b>	
110535	Glove to Wrist
110534	Glove to Elbow
110533	Glove to Axilla
110537	Mitten
110536	Web Spacer
110025	Individual Finger
<b>Arm</b>	
110501	Arm Sleeve
110502	Arm Sleeve and Gauntlet
110503	Arm Sleeve and Shoulder Flap
110504	Arm Sleeve, Gauntlet and Shoulder Flap
110505	Detachable Gauntlet
110516	Forearm Sleeve and Gauntlet

110515	Forearm Sleeve Wrist to Elbow
110016	Arm Band
110013	Half Arm Flap
111140	Stump Sleeve
111141	Stump Sleeve/Shoulder Flap
<b>Torso</b>	
110523	Shrug with Long Sleeves
110524	Shrug with Short Sleeves
110525	Sleeveless Vest
110528	Vest with Short Sleeves
110527	Vest with Long Sleeves
110530	Sleeveless Brief
110532	Brief with Short Sleeves
110531	Brief with Long Sleeves
110558	Sleeveless Body Suit
110561	Suit with Short Sleeves
110560	Suit with Long Sleeves
110018	Torso Band
110034	Turtleneck Detachable
<b>Lower Extremity</b>	
110105	Anklet
110101	Knee Length
110201	Thigh Length
110015	Knee Band
110019	Thigh Band
110022	Leg Band Thigh to Ankle
110035	Thigh Length with Waist Attachment, Chap Style, One Leg
110036	Thigh Length with Waist Attachment, Chap Style, Two Legs
111120	Panty Brief
111119	Panty Girdle
111110	Panty Girdle, Below Knee, Open Pubis
111111	Panty Girdle, Below Knee, Closed Pubis
111122	Panty Girdle, Two Legs, Open Pubis
111101	Waist Height, Two Legs, Closed Pubis
111102	Waist Height, Two Legs, Open Pubis
111103	Waist Height, One Leg, Open Pubis
111112	Waist Height, One Leg, Panty, Open Pubis
111113	Waist Height, One Leg, Panty, Closed Pubis
111104	Chest Height, Two Legs, Pregnancy
111130	Stump Support, Above Knee
111131	Stump Support, Below Knee
110039	Panty, One Leg Stump
111132	Waist Height, One Stump
111133	Waist Height, Two Stumps
111134	Waist Height, One Leg, One Stump, Closed Pubis
111135	Waist Height, One Leg, One Stump, Open Pubis
110538	Foot Glove
110539	Foot Glove to Knee
110570	Foot Glove to Instep
110026	Penis Support

111050	Leg Sleeve with Silicone Band - Thigh - 25-32cm
111051	Leg Sleeve with Silicone Band - Thigh - 29-36cm
111052	Leg Sleeve with Silicone Band - Thigh - 32-39cm
111053	Leg Sleeve with Silicone Band - Thigh - 35-43cm
111054	Leg Sleeve with Silicone Band - Thigh - 42-49cm
111055	Leg Sleeve with Silicone Band - Thigh - 46-53cm
111056	Leg Sleeve with Silicone Band - Thigh - 49-56cm
111057	Leg Sleeve with Silicone Band - Thigh - 53-60cm
<b>Interim RTW Garments</b>	
111090	Face Mask, Head 46 - 53cm
111091	Face Mask, Head 51 - 59cm
111092	Face Mask, Head 56 - 64cm
111093	Chin Strap, Head 46 - 54cm
111094	Chin Strap, Head 51 - 59cm
111095	Chin Strap, Head 56 - 64cm
<b>Upper Extremity</b>	
111059	Vest, Chest 43 - 51cm
11059L	Long Sleeved Vest - Chest - 43-51cm
111060	Vest, Chest 48 - 56cm
111060L	Long Sleeved Vest - Chest - 48-56cm
111061	Vest, Chest 53 - 64cm
111061L	Long Sleeved Vest - Chest - 53-64cm
111062	Vest, Chest 61 - 71cm
111062L	Long Sleeved Vest - Chest - 61-71cm
111063	Vest, Chest 68 - 81cm
111063L	Long Sleeved Vest - Chest - 68-81cm
111064	Vest, Chest 79 - 91cm
111064L	Long Sleeved Vest - Chest - 79-91cm
111065	Vest, Chest 86 - 104cm
111065L	Long Sleeved Vest - Chest - 86-104cm
111066	Vest, Chest 96 - 114cm
111066L	Long Sleeved Vest - Chest - 96-114cm
111066X	Vest - Chest - 109-127cm
111066XL	Long Sleeved Vest - Chest - 109-127cm
111080	Sleeve, Forearm 13 - 17cm
111081	Sleeve, Forearm 15 - 19cm
111082	Sleeve, Forearm 18 - 23cm
111083	Sleeve, Forearm 22 - 26cm
111084	Sleeve, Forearm 26 - 31cm
<b>Hand</b>	
111085	Glove, Palm 12 - 13cm
111086	Glove, Palm 13 - 15cm
111087	Glove, Palm 15 - 17cm
111088	Glove, Palm 17 - 20cm
111088L	Longer Glove - Palm - 17-20cm
111089	Glove, Palm 20 - 25cm
111089L	Longer Glove - Palm - 20-25cm
111097	Glove, Palm 25 - 29cm
111097L	Longer Glove - Palm - 25-29cm
111098	Glove, Palm 26 - 31cm
111098L	Longer Glove - Palm - 26-31cm
<b>Lower Extremity</b>	

111067	Panty Girdle, Hip 48 - 56cm
111068	Panty Girdle, Hip 53 - 61cm
111069	Panty Girdle, Hip 58 - 69cm
111070	Panty Girdle, Hip 66 - 79cm
111071	Panty Girdle, Hip 74 - 89cm
111072	Panty Girdle, Hip 84 - 99cm
111073	Panty Girdle, Hip 96 - 109cm
111074	Panty Girdle, Hip 104 - 127cm
111075	Knee, Ankle 13 - 17cm
111076	Knee, Ankle 14 - 18cm
111077	Knee, Ankle 17 - 20cm
111078	Knee, Ankle 19 - 23cm
111079	Knee, Ankle 20 - 26cm
<b>Classic MTM Garments</b>	
<b>Head and Neck</b>	
PG33	Open Face Mask
PG32	Mask/Helmet, Including Fastenings
PG31	Chin Strap, including Fastenings
PG34	Wide Chin Strap
PG30	Collar, including Fastenings
<b>Arm</b>	
PG10	Single Arm Length, as Required
PG12	Single Arm Length with Band
PG12A	Arm Sleeve with Shoulder Flap
<b>Hand</b>	
PG13	Glove, up to 4cm above Wrist
PG14	Glove, over 4cm above Wrist
PG16	Gauntlet, up to 4cm above Wrist
PG17	Gauntlet, over 4cm above Wrist
PG18	Single Finger
PG19	Web Spacer
<b>Torso</b>	
PG01	Vest, No Sleeves
PG55	Vest with Straps, No Arms
PG56	Vest with One Arm, Short or Long Sleeve
PG02	Vest, Short or Long Sleeves
PG74	Shrug Short Sleeves or Long Sleeves
PG52	Sternal Garment
PG03	Leotard, No Sleeves or Legs
PG04	Leotard, with Sleeves, No Legs
PG05	Single Elastic Trunk Belt
PG06	Double Elastic Trunk Belt
<b>Lower Extremity</b>	
PG57	Panty, Chest Height, Short Legs
PG58	Panty, Chest Height with Straps, Long Legs
PG24	Panty, Long Legs
PG23	Panty, Short Legs
PG72	Pregnancy Panty
PG73	French Knickers
PG22	Thigh Length Stocking, Open/Closed Toe
PG26	Single Leg, Including Waist Attachment
PG27	Single Leg, Hip Style

PG25	Leg Sleeve
PG21	Below Knee Stocking, Open/Closed Toe
PG20	Sock, up to 5cm above Ankle
<b>Head</b>	
NC0503	Elastic Head Dressing (S) 46 - 53cm
NC0504	Elastic Head Dressing (M) 51 - 58.5cm
NC0505	Elastic Head Dressing (L) 56 - 63.5cm
NC0506	Elastic Head Dressing (XL) 61 - 69cm
<b>Upper Extremity</b>	
GM01	Gynecomastia Vest (XXS) 76 - 81cm
GM02	Gynecomastia Vest (XS) 87 - 91cm
GM03	Gynecomastia Vest (S) 92 - 96cm
GM04	Gynecomastia Vest (M) 97 - 102cm
GM05	Gynecomastia Vest (L) 103 - 109cm
GM06	Gynecomastia Vest (XL) 110 - 117cm
GM07	Gynecomastia Vest (XXL) 118 - 125cm
GM01C	Gynecomastia Vest Cropped (XXS) 76 - 81cm
GM02C	Gynecomastia Vest Cropped (XS) 87 - 91cm
GM03C	Gynecomastia Vest Cropped (S) 92 - 96cm
GM04C	Gynecomastia Vest Cropped (M) 97 - 102cm
GM05C	Gynecomastia Vest Cropped (L) 103 - 109cm
GM06C	Gynecomastia Vest Cropped (XL) 110 - 117cm
GM07C	Gynecomastia Vest Cropped (XXL) 118 - 125cm
<b>Hand</b>	
ED30	Finger Sleeve (XS) 3.2 - 4.4cm (1 Metre Length)
ED31	Finger Sleeve (S) 3.5 - 5.4cm (1 Metre Length)
ED32	Finger Sleeve (M) 4.8 - 6.7cm (1 Metre Length)
ED33	Finger Sleeve (L) 6.0 - 7.3cm (1 Metre Length)
ED34	Finger Sleeve (XL) 7.0 - 7.6cm (1 Metre Length)
ED35	Finger Sleeve (XXL) 7.6cm and over (1 Metre Length)
NW01	Mainstay Glove
NW13	Mainstay Glove with Inserts
<b>Lower Extremity</b>	
SSMTM	Scrotal Support, Made to Measure
SS01	OTS Scrotal Support Garment (XS) 58 - 69cm
SS02	OTS Scrotal Support Garment (S) 68 - 79cm
SS03	OTS Scrotal Support Garment (M) 78 - 89cm
SS04	OTS Scrotal Support Garment (L) 88 - 99cm
SS05	OTS Scrotal Support Garment (XL) 97 - 109cm
<b>Premium MTM Garments</b>	
111166	Lip Cover
110014	Ear Flap
110021	Reinforced Palm
111169	Slant Insert
111167	Lining Inside Elbow
111168	Lining Full Elbow
111172	Adjustable Shoulder Flap
20040	Bra Attach
111170	Attached Gauntlet, Body Suit and Vest
110001	Nappy Strap
111193	Contour Pad HD Foam
EB000	Character Bindings and Trims



111190	Character Transfer
110012	Double Waistband
111162	Suspenders
111163	Velcro Tabs
110024	Reinforcement Top of Waist Height
111175	Double Abdominal Panel
111176	Uplift Panel for Abdomen
111161	Reduced Pressure Panel
111194	Reinforcement Panel
111173	Alteration to Waist Height, Post Pregnancy
111174	Pregnancy Support During Alteration
111184	Reinforcement Top of Thigh
111185	Reinforced Inner Thigh of Waist Height
110040	Behind Knee Lining
111186	Reinforced Knee
111187	Reinforced Heel
110020	Extra Heel Reinforcement
111159	Self Enclosed Toes
111160	Soft Enclosed Toes
110027	Pocket / Lining
111164	Zip less than 8" (20cm)
111165	Zip 8"(20cm) and Longer
111191	Silon-TEX Silicone Fabric (per sq. cm)
111198	Adding Silon-TEX to Garment Small
111199	Adding Silon-TEX to Garment Large
111202	Measuring Stand
111000	Pressure Garment Sewing Repair Kit
<b>Classic MTM</b>	
PG07	Bra Cups in Addition to Vest
PG09	Seamless Bra Pocket
PG44	Shoulder Strap (Each)
PG45	Double Fabric Panel/Pocket Lycra
PG40	Pad (Any Size)
PG41	Fastening/Opening to Garment, (Any Size)
PG42	Soft Lining (Each)
PG43	Nappy Strap
PG70	Contour Pad HD Foam
PG46	Multi Skeletal Correction Panel - Minor
PG47	Multi Skeletal Correction Panel - Medium
PG48	Multi Skeletal Correction Panel - Complex
PG49	Alteration - Minor
PG49B	Alteration - Medium
PG49C	Alteration - Complex
PG53	Poly Cotton Garments + 20%
PG71	Character Transfer
EB000	Character Bindings and Trims
PG39	Silon-TEX, Silicone Fabric (per sq. cm)
PG39S	Adding Silon-TEX, Silicone Fabric, Small (< 4 sq. cm)
PG39L	Adding Silon-TEX, Silicone Fabric, Large/Complex (> 4 sq. cm)

### Version History

Version	Compiled by	Date	Description
1	Debra Wright	25/11/2021	First Issue
2	Debra Wright	04/05/2022	Second Issue

## Declaration of Conformity

### For SDO<sup>®</sup> Sensory Dynamic Orthosis

#### Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	SDO Sensory Dynamic Orthosis
Legal Manufacturer: (Name on Label)	Medigarments Ltd, 13a Harrington Mill, Leopold Street, Long Eaton, Nottingham, NG10 4QG United Kingdom
Manufacturers SRN:	Not yet available
Basic UDI-DI:	506059893TF60007B
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	Dynamic compression garments to provide stability, alignment and sensory and proprioceptive feedback to improve postural control, mobility and function.
MDR Classification:	Class 1 [Rule 1]
Notified Body:	Not applicable
EC Certificate:	Not applicable
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745.

#### Declaration Signature:

Date: 4th May 2022  
Location: As above  
Name: Debra Wright  
Position: Product Manager



Signed:

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

## Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN ISO 20417:2021	Medical devices. Information supplied by the manufacturer
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2016	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
EN ISO 10993-1:2018 and applicable parts of the EN ISO 10993 series	Biological evaluation of medical devices – Part 1 Evaluation and testing within a risk management process
MEDDEV 2.7-1 rev 4, June 2016	Guidelines on a Medical Devices Clinical Evaluation: A guide for manufacturers and notified bodies
MEDDEV 2.12-1 rev 8, December 2013	Guidelines on a Medical Device Vigilance System.

## Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/NameA1:A143
<b>SDO ORIGINAL SENSORY DYNAMIC GARMENTS</b>	
PCP05	SDO® Body Suit with 0 - 4 Panels
PCP04	SDO® Body Suit with 5 Panels or more
PCP02	SDO® Leotard with/without sleeves and 0 - 4 panels
PCP01	SDO® Leotard with/without sleeves and 5 panels or more
PCP03	SDO® Vest with/without sleeves and 0 - 4 panels
PCP13	SDO® Gauntlet to below elbow with 0 - 4 panels
PCP12	SDO® Gauntlet to above elbow with 0 - 4 panels
PCP07	SDO® Glove with Sleeve to below elbow and 0 - 4 panels
PCP14	SDO® Glove with Sleeve to above elbow and 0 - 4 panels
PCP06	SDO® Sleeve with 0 - 4 panels
PCP19	SDO® Shorts - Above Knee with 0 - 4 panels
PCP15	SDO® Leggings - Below Knee with 0 - 4 panels
PCP29	SDO® High Waisted Leggings with Shoulder Straps
PCP08	SDO® Sock with 0 - 4 panels
PCP72	SDO® Sleep Suit with 0 - 3 panels
PCP30	SDO® Sleep Shorts with 0 - 3 panels
PCP27	Trunk Stabilising Belt

PCP33S	Sensory Hug Mini - Small - 34 - 49
PCP33M	Sensory Hug Mini - Medium - 49 - 64
PCP33L	Sensory Hug Mini - Large - 64 - 79
PCP34S	Sensory Hug Maxi - Small - 54 - 69
PCP34M	Sensory Hug Maxi - Medium - 69-84
PCP34L	Sensory Hug Maxi - Large - 84 - 99
PCP34XL	Sensory Hug Maxi - Extra Large - 99 - 114
PCP73A	DZ Suit Double Zip
PCP73B	DZ Suit Double Zip, Soft Panels
PCP73C	DZ Suit Double Zip, Expanding Zip
<b>SDO ADVANCED SENSORY DYNAMIC GARMENTS</b>	
SDO01	SDO® Body Suit with 0 - 4 Panels
SDO02	SDO® Body Suit with 5 Panels or more
SDO03	SDO® Leotard with/without sleeves and 0 - 4 panels
SDO04	SDO® Leotard with/without sleeves and 5 panels or more
SDO05	SDO® Vest with/without sleeves and 0 - 4 panels
SDO06	SDO® Gauntlet to below elbow with 0 - 4 panels
SDO07	SDO® Gauntlet to above elbow with 0 - 4 panels
SDO08	SDO® Glove with Sleeve to below elbow and 0 - 4 panels
SDO09	SDO® Glove with Sleeve to above elbow and 0 - 4 panels
SDO10	SDO® Sleeve with 0 - 4 panels
SDO11	SDO® Shorts - Above Knee with 0 - 4 panels
SDO12	SDO® Leggings - Below Knee with 0 - 4 panels
SDO13	SDO® Sock with 0 - 4 panels
SDO14	SDO® Shoulder Stability Orthosis - Single
SDO15	SDO® Shoulder Stability Orthosis - Double
SDO16	SDO® High Waisted Shorts with Shoulder Strap and 0 - 4 panels
SDO17	SDO® Sleep Suit with 0 - 3 panels
SDO18	SDO® Sleep Shorts with 0 - 3 panels
<b>Appendix II – Products which are sold alongside the devices, not devices subject to this DoC.</b>	
PCP10	SDO® FOC Alteration
PCP11	SDO® Minor Alteration
PCP16	SDO® Medium Alteration
PCP17	SDO® Major Alteration
PCP31	SDO® Zip Strip Body
PCP32	SDO® Zip Strip Pair Legs
<b>SDO® Lite Assessment Garments</b>	
SDOL11	SDO® Lite Shorts 48 - 56cm
SDOL12	SDO® Lite Shorts 53 - 61cm
SDOL13	SDO® Lite Shorts 58 - 69cm
SDOL14	SDO® Lite Shorts 66 - 79cm
SDOL15	SDO® Lite Shorts 74 - 89cm
SDOL16	SDO® Lite Shorts 84 - 99cm
SDOL17	SDO® Lite Shorts 96 - 109cm
SDOL18	SDO® Lite Shorts 104 - 127cm
SDOL21	SDO® Lite Vest 43 - 51cm
SDOL22	SDO® Lite Vest 48 - 56cm

SDOL23	SDO® Lite Vest 53 - 64cm
SDOL24	SDO® Lite Vest 61 - 71cm
SDOL25	SDO® Lite Vest 68 - 81cm
SDOL26	SDO® Lite Vest 79 - 91cm
SDOL27	SDO® Lite Vest 86 - 104cm
SDOL28	SDO® Lite Vest 96 - 114cm
SDOL31	SDO® Lite Sleeve 9 - 13cm
SDOL32	SDO® Lite Sleeve 12 - 16cm
SDOL33	SDO® Lite Sleeve 14 - 17cm
SDOL34	SDO® Lite Sleeve 15 - 19cm
SDOL35	SDO® Lite Sleeve 16.5 - 20.5cm
SDOL36	SDO® Lite Sleeve 18 - 22cm
SDOL37	SDO® Lite Sleeve 22 - 27cm
SDOL41	SDO® Lite Left Gauntlet 11 - 14cm
SDOL42	SDO® Lite Left Gauntlet 13 - 16cm
SDOL43	SDO® Lite Left Gauntlet 15 - 18cm
SDOL44	SDO® Lite Left Gauntlet 17 - 21cm
SDOL45	SDO® Lite Left Gauntlet 20 - 25cm
SDOL51	SDO® Lite Right Gauntlet 11 - 14cm
SDOL52	SDO® Lite Right Gauntlet 13 - 16cm
SDOL53	SDO® Lite Right Gauntlet 15 - 18cm
SDOL54	SDO® Lite Right Gauntlet 17 - 21cm
SDOL55	SDO® Lite Right Gauntlet 20 - 25cm
SDOL61	SDO® Lite Sock 13 - 15cm
SDOL62	SDO® Lite Sock 14 - 18cm
SDOL63	SDO® Lite Sock 16.5 - 20cm
SDOL64	SDO® Lite Sock 19 - 23cm
SDOL65	SDO® Lite Sock 20 - 25cm
SDOL71	SDO® Lite Lumbar Belt back depth 17, fits up to 72cm
SDOL72	SDO® Lite Lumbar Belt back depth 21, fits up to 96cm
SDOL73	SDO® Lite Lumbar Belt back depth 29, fits up to 104cm
SDOL74	SDO® Lite Lumbar Belt back depth 34, fits up to 126cm
<b>ProTEM ASSESSMENT GARMENTS</b>	
PCP23A	Full SDO® Assessment Kit - Adult
PCP23B	Full SDO® Assessment Kit - Paediatric
PCP63	SDO® ProTEM Sleeve
PCP69	SDO® ProTEM Gauntlet
PCP21	SDO® ProTEM Lumbar Belt - Paediatric
PCP22	SDO® ProTEM Lumbar Belt - Adult
PCP70	SDO® ProTEM Sock
PCP71	SDO® ProTEM AX Suit with Crotch
PCP71A	SDO® ProTEM AX Suit without Crotch

### Version History

Version	Compiled by	Date	Description
1	Debra Wright	25/11/2021	First Issue
2	Debra Wright	04/05/2022	Second Issue