



Life Changing Innovation

# EU & UK Declaration of Conformity

This European and UK Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
Aspen Medical Products, LLC	6481 Oak Canyon, Irvine, CA 92618 USA	US-MF-000001571

EU AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Telephone/email
Emergo Europe	Westervoortsedijk 60, 6827 AT, Arnhem, The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

UK RESPONSIBLE PERSON			
Name of Company	Address	SRN	Telephone/email
Promedics Orthopaedics Ltd.	Port Glasgow Industrial Estate, Gareloch Road, Port Glasgow, Scotland, UK, PA14 5XH	GB-MF-000008558	01475 746400 - phone enquiries@promedics.co.uk

PRODUCT IDENTIFICATION			
Generic Device Group (GDG)			
TLSO			
Product Name	Product Code / Catalog Number		Basic UDI-DI
Aspen Active P-TLSO Aspen Evergreen Aspen Contour Aspen Horizon Aspen TLSO Align Orthosis	Aspen OTS Aspen Sierra Lower Spine Aspen Summit Aspen Vista Lower Spine Aspen Elite VRTX TLSO	See attached list	081824901TLSoEF
Intended Purpose			
To provide motion restriction and stability of the thoracic-lumbar-sacral spine.			

RISK CLASS FOR MEDICAL DEVICES		
EU Device Classification	UK Device Classification	Common Specifications
Class I, Rule 1 per Annex VIII of MDR (EU) 2017/745	Class I per Part II of the UK MDR 2002, Annex IX (as modified by Part II of Schedule 2A to the UK MDR 2002)	None

Aspen Medical Products, LLC declares that the above-mentioned products meet the provision of the following:

- MDR (EU) 2017/745
- UK Medical Devices Regulations 2002

**COMPANY REPRESENTATIVE:** John Hamilton  
**TITLE:** Vice President, Quality and Strategic Initiatives  
**PLACE:** Irvine, CA USA

**SIGNATURE:**   
**DATE:** December 20, 2024

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REF	Description	UDI
491101	ASPEN ACTIVE P-TLSO	818249013695
491105	ASPEN ACTIVE P-TLSO EXTENSION PANEL	818249013787
501221	SIERRA TLSO ADJUSTABLE	818249013664
501321	SIERRA TLSO, UPGRADE KIT, ADJUSTABLE	818249013688
501322	SIERRA LS EXTENSION PANEL	818249013671
502212	ASPEN SIERRA HYPEREXTENSION TLSO, SMALL	818249014623
502213	ASPEN SIERRA HYPEREXTENSION TLSO, MEDIUM	818249014630
502214	ASPEN SIERRA HYPEREXTENSION TLSO, LARGE	818249014647
502215	ASPEN SIERRA HYPEREXTENSION TLSO, EXTRA LARGE	818249014654
504571	ASPEN 457 TLSO SM	818249013473
504572	ASPEN 457 TLSO M	818249013480
504573	ASPEN 457 TLSO L (UNIVERSAL)	818249013503
504574	ASPEN 457 TLSO XL	818249013497
514563	FLX 456 TLSO	818249016511
514643	FLX 464 TLSO	818249016856
514646	FLX 464 TLSO	818249016849
590601	ELITE TLSO, X-SMALL	818249015439
590602	ELITE TLSO, SMALL	818249015446
590603	ELITE TLSO, MEDIUM	818249015453
590604	ELITE TLSO, LARGE	818249015460
590605	ELITE TLSO, X-LARGE	818249015477
590606	ELITE TLSO, XX-LARGE	818249015484
590607	ELITE TLSO, XXX-LARGE	818249015569
591601	ELITE TLSO, X-SMALL	818249015491
591602	ELITE TLSO, SMALL	818249015507
591603	ELITE TLSO, MEDIUM	818249015514
591604	ELITE TLSO, LARGE	818249015521
591605	ELITE TLSO, X-LARGE	818249015538
591606	ELITE TLSO, XX-LARGE	818249015545
591607	ELITE TLSO, XXX-LARGE	818249015552
991030	ASPEN TLSO, SHORT/SMALL	818249010106
991031	ASPEN TLSO, SHORT/LARGE	818249011585
991035	ASPEN LSO/TLSO REPLACEMENT PADS	818249011929
991050	ASPEN TLSO UPGRADE KIT, TALL	818249011943
991051	ASPEN TLSO UPGRADE KIT, SHORT	818249011950
991053	ASPEN TLSO UPGRADE KIT, X-SHORT	818249010328
991070	ASPEN TLSO, TALL/SMALL	818249010113
991071	ASPEN TLSO, TALL/LARGE	818249011592
992710	SUMMIT 456, ADJUSTABLE	818249012179
992720	SUMMIT 456, SMALL	818249011271
992730	SUMMIT 456, MEDIUM	818249011288
992740	SUMMIT 456, LARGE	818249011295

<b>REF</b>	<b>Description</b>	<b>UDI</b>
992750	SUMMIT 456, X-LARGE	818249011301
993640	VISTA 464 TLSO	818249011356
993642	VISTA REPLACEMENT PADS	818249012469
993644	VISTA 464 TLSO UPGRADE KIT	818249012520
993740	HORIZON 456	818249012117
994151	CONTOUR TLSO SHOULDER STRAP UPGRADE, SHORT	818249010427
994152	CONTOUR TLSO SHOULDER STRAP UPGRADE, TALL	818249010434
994255	CONTOUR TLSO CHEST PANEL UPGRADE, SMALL	818249011394
994260	CONTOUR TLSO CHEST PANEL UPGRADE, MEDIUM	818249010441
994265	CONTOUR TLSO CHEST PANEL UPGRADE, LARGE	818249011400
994351	CONTOUR TLSO SPK COMPLETE, MEDIUM	818249010168
994352	CONTOUR TLSO SPK COMPLETE, LARGE	818249010175
994353	CONTOUR TLSO SPK COMPLETE, X-LARGE	818249010182
994354	CONTOUR TLSO SPK COMPLETE, XX-LARGE	818249011455
994455	CONTOUR TLSO SPK UPGRADE, SMALL	818249011493
994460	CONTOUR TLSO SPK UPGRADE, MEDIUM	818249011509
994465	CONTOUR TLSO SPK UPGRADE, LARGE	818249011516
994470	CONTOUR TLSO SPK REPLACEMENT PADS, BLACK	818249012490
994740	HORIZON PRO 456	818249015859
994750	HORIZON PRO 464/456 TLSO	818249016832
994760	HORIZON PRO 464 TLSO	818249016863
995002	VRTX SHOULDER STRAP KIT	818249016276
995610	VRTX TLSO - STANDARD	818249016153
995613	VRTX LOWER SPINE REPLACEMENT PADS - STANDARD	818249016160
995620	VRTX TLSO - XS	818249016177
995623	VRTX LOWER SPINE REPLACEMENT PADS - XS	818249016184
995630	VRTX TLSO - XL	818249016191
995633	VRTX LOWER SPINE REPLACEMENT PADS - XL	818249016207
997040	ALIGN ORTHOSIS – XS	818249016665
997045	ALIGN ORTHOSIS REPLACEMENT PADS – UNIVERSAL	818249016689
997050	ALIGN ORTHOSIS - STD	818249016672
36-5611	EVERGREEN TLSO, ADJUSTABLE	818249012704
993645/L	TLSO CONTOUR W/VISTA UPGRADE KIT L	818249015293
993645/M	TLSO CONTOUR W/VISTA UPGRADE KIT M	818249015286
993645/S	TLSO CONTOUR W/VISTA UPGRADE KIT S	818249015279
993645/XL	TLSO CONTOUR W/VISTA UPGRADE KIT XL	818249015309