



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)			
LUMBAR			
Product Name		Product Code / Catalog Number	Basic UDI-DI
Aspen Contour	Aspen OTS	See attached list	081824901LSOH8
Aspen Elite	Aspen QuikDraw		
Aspen Evergreen	Aspen Sierra Lower Spine		
Aspen Horizon	Aspen Summit		
Aspen LSO	Aspen Vista Lower Spine		
Aspen Lumbar	VRTX LSO		
Intended Purpose			
To provide motion restriction and stability of the 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: February 02, 2024

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REF	Description	UDI
501111	SIERRA LSO ADJUSTABLE	818249013657
506423	ASPEN 642 LUMBAR	818249013114
506483	ASPEN 648 LSO	818249013121
506503	ASPEN 650 LSO	818249013138
506505	UNIVERSAL EXTENSION PANEL	818249013282
516273	FLX 627 LSO	818249016481
516313	FLX 631 LSO	818249016498
516373	FLX 637 LSO	818249016504
516393	FLX 639 LSO	818249016535
580101	ASPEN LUMBAR, XS	818249012742
580102	ASPEN LUMBAR, S	818249012759
580103	ASPEN LUMBAR, M	818249012766
580104	ASPEN LUMBAR, L	818249012773
580105	ASPEN LUMBAR, XL	818249012780
580106	ASPEN LUMBAR, XXL	818249012797
590201	ASPEN ELITE ACTIVE, X-SMALL	818249012803
590202	ASPEN ELITE ACTIVE, SMALL	818249012810
590203	ASPEN ELITE ACTIVE, MEDIUM	818249012827
590204	ASPEN ELITE ACTIVE, LARGE	818249012834
590205	ASPEN ELITE ACTIVE, X-LARGE	818249012841
590206	ASPEN ELITE ACTIVE, XX-LARGE	818249012858
590207	ASPEN ELITE ACTIVE, XXX-LARGE	818249015576
590250	ELITE PELOTTE PAD	818249013510
590260	ELITE ACTIVE POSTERIOR PANEL	818249014616
590301	ASPEN ELITE ACTIVE +, X-SMALL	818249012926
590302	ASPEN ELITE ACTIVE +, SMALL	818249012933
590303	ASPEN ELITE ACTIVE +, MEDIUM	818249012940
590304	ASPEN ELITE ACTIVE +, LARGE	818249012957
590305	ASPEN ELITE ACTIVE +, X-LARGE	818249012964
590306	ASPEN ELITE ACTIVE +, XX-LARGE	818249012971
590307	ASPEN ELITE ACTIVE +, XXX-LARGE	818249015590
590360	ELITE ACTIVE + POSTERIOR PANEL	818249014661
590401	ASPEN ELITE PRO, X-SMALL	818249012988
590402	ASPEN ELITE PRO, SMALL	818249012995
590403	ASPEN ELITE PRO, MEDIUM	818249013008
590404	ASPEN ELITE PRO, LARGE	818249013015
590405	ASPEN ELITE PRO, X-LARGE	818249013022

REF	Description	UDI
590406	ASPEN ELITE PRO, XX-LARGE	818249013039
590407	ASPEN ELITE PRO, XXX-LARGE	818249015613
590501	ASPEN ELITE PRO +, X-SMALL	818249013046
590502	ASPEN ELITE PRO +, SMALL	818249013053
590503	ASPEN ELITE PRO +, MEDIUM	818249013060
590504	ASPEN ELITE PRO +, LARGE	818249013077
590505	ASPEN ELITE PRO +, X-LARGE	818249013084
590506	ASPEN ELITE PRO +, XX-LARGE	818249013091
590507	ASPEN ELITE PRO +, XXX-LARGE	818249015637
590555	ELITE EXTENSION PANEL	818249014609
591201	ASPEN ELITE ACTIVE, X-SMALL	818249013596
591202	ASPEN ELITE ACTIVE, SMALL	818249013602
591203	ASPEN ELITE ACTIVE, MEDIUM	818249013619
591204	ASPEN ELITE ACTIVE, LARGE	818249013626
591205	ASPEN ELITE ACTIVE, X-LARGE	818249013633
591206	ASPEN ELITE ACTIVE, XX-LARGE	818249013640
591207	ASPEN ELITE ACTIVE, XXX-LARGE	818249015583
591301	ASPEN ELITE ACTIVE +, X-SMALL	818249013534
591302	ASPEN ELITE ACTIVE +, SMALL	818249013541
591303	ASPEN ELITE ACTIVE +, MEDIUM	818249013558
591304	ASPEN ELITE ACTIVE +, LARGE	818249013565
591305	ASPEN ELITE ACTIVE +, X-LARGE	818249013572
591306	ASPEN ELITE ACTIVE +, XX-LARGE	818249013589
591307	ASPEN ELITE ACTIVE +, XXX-LARGE	818249015606
591401	ASPEN ELITE PRO, X-SMALL	818249015316
591402	ASPEN ELITE PRO, SMALL	818249015323
591403	ASPEN ELITE PRO, MEDIUM	818249015330
591404	ASPEN ELITE PRO, LARGE	818249015347
591405	ASPEN ELITE PRO, X-LARGE	818249015354
591406	ASPEN ELITE PRO, XX-LARGE	818249015361
591407	ASPEN ELITE PRO, XXX-LARGE	818249015620
591501	ASPEN ELITE PRO +, X-SMALL	818249015378
591502	ASPEN ELITE PRO +, SMALL	818249015385
591503	ASPEN ELITE PRO +, MEDIUM	818249015392
591504	ASPEN ELITE PRO +, LARGE	818249015408
591505	ASPEN ELITE PRO +, X-LARGE	818249015415
591506	ASPEN ELITE PRO +, XX-LARGE	818249015422

REF	Description	UDI
591507	ASPEN ELITE PRO +, XXX-LARGE	818249015644
990005	ASPEN THERAPY PACK	818249012124
990020	ASPEN LSO LOPRO, SMALL	818249011103
990021	ASPEN LSO LOPRO, LARGE	818249010779
990022	ASPEN LSO LOPRO, X-LARGE	818249010786
990025	ASPEN LSO LOPRO REPLACEMENT PADS	818249011868
990027	ASPEN LSO LOPRO REPLACEMENT PADS, X-LARGE	818249012674
990040	ASPEN LSO, SHORT/SMALL	818249010311
990041	ASPEN LSO, SHORT/LARGE	818249010793
990050	CONTOUR LSO, X-SMALL	818249010847
990051	CONTOUR LSO, SMALL	818249010854
990052	CONTOUR LSO, MEDIUM	818249010861
990053	CONTOUR LSO, LARGE	818249010878
990054	CONTOUR LSO, X-LARGE	818249010885
990055	CONTOUR LSO, XX-LARGE	818249010892
990060	ASPEN LSO, TALL/SMALL	818249010908
990061	ASPEN LSO, TALL/LARGE	818249010915
992122	CONTOUR LSO REPLACEMENT PAD, 12"	818249012483
992125	CONTOUR LSO REPLACEMENT PAD, 15"	818249011981
992212	CONTOUR LSO, 12"	818249010991
992215	CONTOUR LSO, 15"	818249011004
992310	SUMMIT 637, ADJUSTABLE	818249012148
992320	SUMMIT 637, SMALL	818249011110
992330	SUMMIT 637, MEDIUM	818249011127
992340	SUMMIT 637, LARGE	818249011134
992380	SUMMIT 637, X-LARGE	818249012056
992420	SUM ADJ 637 PLUS	818249011158
992505	ASPEN EXTENSION PANEL	818249012155
992510	SUMMIT 631, ADJUSTABLE	818249012162
992520	SUMMIT 631, SMALL	818249011196
992530	SUMMIT 631, MEDIUM	818249011202
992540	SUMMIT 631, LARGE	818249011219
992550	SUMMIT 631, X-LARGE	818249011226
992620	SUM ADJ 631 PLUS	818249011233
993005	QUIKDRAW COLD THERAPY PACK	818249012537
993010	QUIKDRAW PRO, WHITE, SMALL	818249011028
993011	QUIKDRAW PRO, BLACK, SMALL	818249010120

REF	Description	UDI
993020	QUIKDRAW PRO, WHITE, MEDIUM	818249011035
993021	QUIKDRAW PRO, BLACK, MEDIUM	818249010137
993030	QUIKDRAW PRO, WHITE, LARGE	818249011042
993031	QUIKDRAW PRO, BLACK, LARGE	818249010144
993040	QUIKDRAW PRO, WHITE, X-LARGE	818249011059
993041	QUIKDRAW PRO, BLACK, X-LARGE	818249010151
993060	QUIKDRAW EXTENSION PANEL, WHITE	818249012506
993061	QUIKDRAW EXTENSION PANEL, BLACK	818249012513
993080	QUIKDRAW PRO, WHITE, X-SMALL	818249010342
993081	QUIKDRAW PRO, BLACK, X-SMALL	818249010403
993090	QUIKDRAW PRO, WHITE, XX-LARGE	818249011318
993091	QUIKDRAW PRO, BLACK, XX-LARGE	818249010410
993100	QUIKDRAW RIGID ANTERIOR PANEL, WHITE, REGULAR	818249010359
993101	QUIKDRAW RIGID ANTERIOR PANEL, WHITE, LARGE	818249011066
993110	QUIKDRAW RAP REPLACEMENT PAD, REGULAR	818249011998
993111	QUIKDRAW RAP REPLACEMENT PAD, LARGE	818249012001
993200	QUIKDRAW RIGID ANTERIOR PANEL, BLACK, REGULAR	818249011080
993201	QUIKDRAW RIGID ANTERIOR PANEL, BLACK, LARGE	818249011097
993340	VISTA LSO LOPRO	818249011325
993440	VISTA LUMBAR	818249011332
993540	VISTA LSO	818249011349
993710	HORIZON 627	818249012087
993720	HORIZON 631	818249012094
993730	HORIZON 637	818249012100
993735	HORIZON 639	818249013398
993745	HORIZON EXTENSION PANEL	818249012131
994710	HORIZON PRO 627	818249015811
994720	HORIZON PRO 631	818249015828
994730	HORIZON PRO 637	818249015835
994735	HORIZON PRO 639	818249015842
995010	QUIKDRAW RAP, BLACK, X-SMALL	818249011523
995011	QUIKDRAW RAP, WHITE, X-SMALL	818249011530
995020	QUIKDRAW RAP, BLACK, SMALL	818249011547
995021	QUIKDRAW RAP, WHITE, SMALL	818249011554
995030	QUIKDRAW RAP, BLACK, MEDIUM	818249011561
995031	QUIKDRAW RAP, WHITE, MEDIUM	818249011578
995040	QUIKDRAW RAP, BLACK, LARGE	818249011608

REF	Description	UDI
995041	QUIKDRAW RAP, WHITE, LARGE	818249011615
995050	QUIKDRAW RAP, BLACK, X-LARGE	818249011622
995051	QUIKDRAW RAP, WHITE, X-LARGE	818249011639
995060	QUIKDRAW RAP, BLACK, XX-LARGE	818249011646
995061	QUIKDRAW RAP, WHITE, XX-LARGE	818249011653
995410	VRTX LSO - STANDARD	818249016320
995420	VRTX LSO - XS	818249016337
995430	VRTX LSO - XL	818249016344
36-2602	EVERGREEN LUMBAR LITE, X-SMALL	818249012346
36-2603	EVERGREEN LUMBAR LITE, SMALL	818249012353
36-2604	EVERGREEN LUMBAR LITE, MEDIUM	818249012360
36-2605	EVERGREEN LUMBAR LITE, LARGE	818249012377
36-2606	EVERGREEN LUMBAR LITE, X-LARGE	818249012384
36-2607	EVERGREEN LUMBAR LITE, XX-LARGE	818249012391
36-2702	EVERGREEN LUMBAR, X-SMALL	818249010526
36-2703	EVERGREEN LUMBAR, SMALL	818249010533
36-2704	EVERGREEN LUMBAR, MEDIUM	818249010540
36-2705	EVERGREEN LUMBAR, LARGE	818249010557
36-2706	EVERGREEN LUMBAR, X-LARGE	818249010564
36-2707	EVERGREEN LUMBAR, XX-LARGE	818249010571
36-2711	EVERGREEN LUMBAR, ADJUSTABLE	818249012698
36-3102	EVERGREEN LSO LOPRO, X-SMALL	818249010458
36-3103	EVERGREEN LSO LOPRO, SMALL	818249010465
36-3104	EVERGREEN LSO LOPRO, MEDIUM	818249010472
36-3105	EVERGREEN LSO LOPRO, LARGE	818249010489
36-3106	EVERGREEN LSO LOPRO, X-LARGE	818249010496
36-3107	EVERGREEN LSO LOPRO, XX-LARGE	818249010502
36-3111	EVERGREEN LSO LOPRO, ADJUSTABLE	818249012407
36-3702	EVERGREEN LSO, X-SMALL	818249010519
36-3703	EVERGREEN LSO, SMALL	818249010045
36-3704	EVERGREEN LSO, MEDIUM	818249010052
36-3705	EVERGREEN LSO, LARGE	818249010069
36-3706	EVERGREEN LSO, X-LARGE	818249010076
36-3707	EVERGREEN LSO, XX-LARGE	818249010588
36-3711	EVERGREEN LSO, ADJUSTABLE	818249012414