



Life Changing Innovation

# Declaration of Conformity

This European 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

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Telephone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

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 TLSO	Aspen Vista Lower Spine		
Aspen Lumbar			
Intended Purpose			
To provide motion restriction and stability of the lumbar-sacral spine.			

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	Common Specifications
Class I Rule 1	None

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

- MDR (EU) 2017/745

**COMPANY REPRESENTATIVE:** John Hamilton

**TITLE:** Vice President, Quality and Strategic Initiatives

**PLACE:** Irvine, CA USA

**SIGNATURE:**

**DATE:** January 09, 2023

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<b>REF</b>	<b>Description</b>	<b>UDI</b>
990005	ASPEN THERAPY PACK	818249012124
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
992122	CONTOUR LSO REPLACEMENT PAD, 12"	818249012483
992125	CONTOUR LSO REPLACEMENT PAD, 15"	818249011981
992212	CONTOUR LSO, 12"	818249010991
992215	CONTOUR LSO, 15"	818249011004
590101	ASPEN ELITE COMFORT, X-SMALL	818249012865
590102	ASPEN ELITE COMFORT, SMALL	818249012872
590103	ASPEN ELITE COMFORT, MEDIUM	818249012889
590104	ASPEN ELITE COMFORT, LARGE	818249012896
590105	ASPEN ELITE COMFORT, X-LARGE	818249012902
590106	ASPEN ELITE COMFORT, XX-LARGE	818249012919
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
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
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
993710	HORIZON 627	818249012087
993720	HORIZON 631	818249012094
993730	HORIZON 637	818249012100
993735	HORIZON 639	818249013398
993745	HORIZON EXTENSION PANEL	818249012131

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
990060	ASPEN LSO, TALL/SMALL	818249010908
990061	ASPEN LSO, TALL/LARGE	818249010915
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
506423	ASPEN 642 LUMBAR	818249013114
506483	ASPEN 648 LSO	818249013121
506503	ASPEN 650 LSO	818249013138
506505	UNIVERSAL EXTENSION PANEL	818249013282
993005	QUIKDRAW COLD THERAPY PACK	818249012537
993010	QUIKDRAW PRO, WHITE, SMALL	818249011028
993011	QUIKDRAW PRO, BLACK, SMALL	818249010120
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
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
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
501111	SIERRA LSO ADJUSTABLE	818249013657
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
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
992505	ASPEN EXTENSION PANEL	818249012155
993340	VISTA LSO LOPRO	818249011325
993440	VISTA LUMBAR	818249011332
993540	VISTA LSO	818249011349