



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)			
CERVICAL			
Product Name		Product Code / Catalog Number	Basic UDI-DI
Aspen Collar Aspen CTO Aspen Sierra Collar Aspen Vista Collar	Aspen Vista CTO VRTX Collar VRTX CTO VRTX CTLSO	See attached list	081824901CERVICALSB
Intended Purpose			
To provide motion restriction of the cervical 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:** November 03, 2023

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REF Number	Product Description	UDI
983102	ASPEN PEDIATRIC COLLAR, PD4	818249010366
983104	ASPEN PEDIATRIC COLLAR, PD5	818249010373
983106	ASPEN PEDIATRIC COLLAR, PD3	818249010380
983108	ASPEN COLLAR, SHORT	818249010618
983109	ASPEN COLLAR FRONT PANEL, SHORT	818249012544
983110	ASPEN COLLAR, REGULAR	818249010625
983111	ASPEN COLLAR FRONT PANEL, REGULAR	818249012551
983112	ASPEN COLLAR, TALL	818249010632
983113	ASPEN COLLAR, FRONT PANEL, TALL	818249012568
983114	ASPEN COLLAR, X-TALL	818249010649
983115	ASPEN COLLAR FRONT PANEL, X-TALL	818249012575
983116	ASPEN PEDIATRIC COLLAR BACK PANEL, PD3/PD4/PD5	818249012582
983118	ASPEN COLLAR BACK PANEL, SMALL	818249011714
983119	ASPEN COLLAR BACK PANEL, LARGE	818249011721
983120	ASPEN COLLAR BACK PANEL, STANDARD	818249011738
983122	ASPEN PEDIATRIC COLLAR SET, PD4	818249010199
983124	ASPEN PEDIATRIC COLLAR SET, PD5	818249010205
983125	SIERRA UNIVERSAL COLLAR, ADULT	818249010694
983126	ASPEN PEDIATRIC COLLAR SET, PD3	818249010212
983128	ASPEN COLLAR SET, SHORT	818249010656
983130	ASPEN COLLAR SET, REGULAR	818249010663
983132	ASPEN COLLAR SET, TALL	818249010670
983134	ASPEN COLLAR SET, X-TALL	818249010687
983150	SIERRA UNIVERSAL COLLAR, PEDIATRIC	818249010700
983159	ASPEN COLLAR REPLACEMENT PADS, UNIVERSAL	818249011660
983161	ASPEN COLLAR BACK PANEL REPLACEMENT PAD, SMALL	818249011745
983190	ASPEN PEDIATRIC COLLAR, PD1	818249010236
983192	ASPEN PEDIATRIC COLLAR SET, PD1	818249010243
983195	ASPEN PEDIATRIC COLLAR, PD2	818249010397
983197	ASPEN PEDIATRIC COLLAR SET, PD2	818249010250
983199	ASPEN PEDIATRIC COLLAR REPLACEMENT PADS	818249010267
983301	ASPEN PEDIATRIC CTO	818249010274
983302	ASPEN PEDIATRIC CTO REPLACEMENT PADS	818249010281
983308	ASPEN CTO, SHORT	818249010748
983309	ASPEN CTO FRONT PANEL, SHORT	818249011776
983310	ASPEN CTO, REGULAR	818249010755
983311	ASPEN CTO FRONT PANEL, REGULAR	818249011783
983312	ASPEN CTO, TALL	818249010809

983313	ASPEN CTO FRONT PANEL, TALL	818249011790
983314	ASPEN CTO, X-TALL	818249010762
983315	ASPEN CTO FRONT PANEL, X-TALL	818249012612
983318	ASPEN CTO BACK PANEL, SMALL	818249012629
983319	ASPEN CTO BACK PANEL, STANDARD	818249012636
983320	ASPEN CTO REPLACEMENT PADS	818249010298
983321	ASPEN CTO BACK PANEL, LARGE	818249012643
983324	ASPEN CTO VEST	818249012667
983330	ASPEN CONTROL CLAMPS	818249010304
984000	VISTA COLLAR	818249010090
984002	VISTA COLLAR SET	818249010717
984006	VISTA COLLAR BACK PANEL, STANDARD	818249011813
984008	VISTA COLLAR BACK PANEL, LARGE	818249011677
984020	VISTA COLLAR REPLACEMENT PADS	818249011684
984028	VISTA COLLAR BACK PANEL REPLACEMENT PAD, LARGE	818249011837
984100	VISTA TX COLLAR	818249010724
984102	VISTA TX COLLAR SET	818249010731
984106	VISTA TX COLLAR BACK PANEL	818249013701
984120	VISTA TX REPLACEMENT PADS	818249011691
984200	VISTA MULTIPOST COLLAR	818249012063
984202	VISTA MULTIPOST COLLAR SET	818249012070
984220	VISTA MULTIPOST REPLACEMENT PADS	818249012216
984250	VISTA MULTIPOST THERAPY COLLAR	818249012728
984252	VISTA THERAPY COLLAR, REPLACEMENT PAD SET	818249013299
984255	VISTA THERAPY COLLAR, REPLACEMENT CHIN PAD	818249013305
984257	REPLACEMENT THERAPY PACK	818249013312
984300	VISTA II COLLAR	818249015989
984302	VISTA II COLLAR SET	818249015996
984320	VISTA II COLLAR REPLACEMENT PADS	818249016016
984350	VISTA II COLLAR BACK PANEL, LARGE	818249016009
984352	VISTA II COLLAR BACK PANEL, LARGE REPLACEMENT PAD	818249016450
984504	VISTA CTO UPGRADE KIT, ANTERIOR	818249012223
984510	VISTA CTO	818249010083
984520	VISTA CTO4/VISTA CTO REPLACEMENT PADS	818249011851
984550	VISTA CTO4	818249012230
984554	VISTA CTO4 UPGRADE KIT, POSTERIOR	818249012247
984600	VISTA ICU BACK PANEL	818249012254
984620	VISTA ICU BACK PANEL REPLACEMENT PADS	818249012261
984650	VISTA II CTLSO UPGRADE KIT	818249016399

984660	VISTA II CTLSO UPGRADE KIT - XS	818249016405
984680	VISTA II CTLSO - STANDARD	818249016429
984690	VISTA II CTLSO - XS	818249016436
984700	VISTA II CTLSO - XL	818249016443
985001	VRTX MULTIPOST COLLAR	818249015682
985003	VRTX MULTIPOST COLLAR SET	818249015712
985005	VRTX STANDARD BACK PANEL	818249015743
985007	VRTX LARGE BACK PANEL	818249015750
985009	VRTX SMALL BACK PANEL	818249015767
985011	VRTX COLLAR	818249015699
985013	VRTX COLLAR SET	818249015729
985030	VRTX COLLAR REPLACEMENT PADS	818249015774
985031	VRTX COLLAR MULTIPOST REPLACEMENT PADS	818249016054
985070	VRTX COLLAR LARGE BACK PANEL REPLACEMENT PAD	818249015781
985101	VRTX TX COLLAR	818249015705
985103	VRTX TX COLLAR SET	818249015736
985105	VRTX TX COLLAR BACK PANEL	818249015903
985130	VRTX TX COLLAR REPLACEMENT PADS	818249015910
985510	VRTX CTO	818249016023
985512	VRTX CTO UPGRADE KIT — ANTERIOR	818249016146
985514	VRTX CTO4 UPGRADE KIT — POSTERIOR	818249016139
985530	VRTX CTO4/VRTX CTO REPLACEMENT PADS	818249016030
985550	VRTX CTO4	818249016047
985600	VRTX COLLAR ICU BACK PANEL	818249015804
985601	VRTX COLLAR ICU REPLACEMENT PAD	818249015798
985611	VRTX CTLSO - UPGRADE KIT STANDARD/XL	818249016221
985621	VRTX CTLSO – UPGRADE KIT XSMALL	818249016238
985635	VRTX CTLSO EXTENDED WEAR PADS	818249016382
985640	VRTX CTLSO – XS	818249016283
985650	VRTX CTLSO – STANDARD	818249016290
985660	VRTX CTLSO – XL	818249016306
985661	VRTX CTLSO EXPANSION KIT ACCESSORIES	818249016313
987370	ASPEN VISTA CERVICAL COLLAR FRONT PANEL & ASPEN CERVICAL COLLAR SMALL BACK PANEL	818249013978