



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)		
ANKLE-FOOT		
Product Name	Product Code / Catalog Number	Basic UDI-DI
Traverse Air Walker Aspen M2 AFO	See attached list	081824901AFOEA
Intended Purpose		
An ankle, foot and/or lower leg orthosis for stabilization and positioning.		

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: October 31, 2024

REF	DESCRIPTION	UDI
653001	TRAVERSE AIR WALKER SHORT XS	818249014678
653002	TRAVERSE AIR WALKER SHORT S	818249014685
653003	TRAVERSE AIR WALKER SHORT M	818249014692
653004	TRAVERSE AIR WALKER SHORT L	818249014708
653005	TRAVERSE AIR WALKER SHORT XL	818249014715
653011	TRAVERSE AIR WALKER TALL XS	818249014722
653012	TRAVERSE AIR WALKER TALL S	818249014739
653013	TRAVERSE AIR WALKER TALL M	818249014746
653014	TRAVERSE AIR WALKER TALL L	818249014753
653015	TRAVERSE AIR WALKER TALL XL	818249014760
640102	ASPEN M2 AFO, ANTERIOR RIGHT, SMALL	818249014937
640103	ASPEN M2 AFO, ANTERIOR RIGHT, MEDIUM	818249014944
640104	ASPEN M2 AFO, ANTERIOR RIGHT, LARGE	818249014951
640202	ASPEN M2 AFO, ANTERIOR LEFT, SMALL	818249014975
640203	ASPEN M2 AFO, ANTERIOR LEFT, MEDIUM	818249014982
640204	ASPEN M2 AFO, ANTERIOR LEFT, LARGE	818249014999
640112	ASPEN M2 AFO, POSTERIOR RIGHT, SMALL	818249015019
640113	ASPEN M2 AFO, POSTERIOR RIGHT, MEDIUM	818249015026
640114	ASPEN M2 AFO, POSTERIOR RIGHT, LARGE	818249015033
640115	ASPEN M2 AFO, POSTERIOR RIGHT, X-LARGE	818249015040
640212	ASPEN M2 AFO, POSTERIOR LEFT, SMALL	818249015057
640213	ASPEN M2 AFO, POSTERIOR LEFT, MEDIUM	818249015064
640214	ASPEN M2 AFO, POSTERIOR LEFT, LARGE	818249015071
640215	ASPEN M2 AFO, POSTERIOR LEFT, X-LARGE	818249015088
655001	TRAVERSE AIR WALKER - SHORT, SET - XS	818249016733
655002	TRAVERSE AIR WALKER - SHORT, SET - S	818249016740
655003	TRAVERSE AIR WALKER - SHORT, SET - M	818249016757
655004	TRAVERSE AIR WALKER - SHORT, SET - L	818249016764
655005	TRAVERSE AIR WALKER - SHORT, SET - XL	818249016771
655011	TRAVERSE AIR WALKER - TALL, SET - XS	818249016788
655012	TRAVERSE AIR WALKER - TALL, SET - S	818249016795
655013	TRAVERSE AIR WALKER - TALL, SET - M	818249016801
655014	TRAVERSE AIR WALKER - TALL, SET - L	818249016818
655015	TRAVERSE AIR WALKER - TALL, SET - XL	818249016825