



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)

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

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 17, 2022

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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