



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)		
KNEE		
Product Name	Product Code / Catalog Number	Basic UDI-DI
Aspen Hinged Knee Aspen ROM Knee Aspen Ci Knee	See attached list	081824901KNEEAU
Intended Purpose		
To provide medial or lateral forces on the knee joint.		

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: May 13, 2021

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REF	Description	UDI
648001	ASPEN HINGED KNEE, XS	818249014173
648002	ASPEN HINGED KNEE, S	818249014180
648003	ASPEN HINGED KNEE, M	818249014197
648004	ASPEN HINGED KNEE, L	818249014203
648005	ASPEN HINGED KNEE, XL	818249014210
648006	ASPEN HINGED KNEE, XXL	818249014227
648011	ASPEN HINGED KNEE, UNIV	818249014166
648101	ASPEN ROM KNEE, XS	818249014104
648102	ASPEN ROM KNEE, S	818249014111
648103	ASPEN ROM KNEE, M	818249014128
648104	ASPEN ROM KNEE, L	818249014135
648105	ASPEN ROM KNEE, XL	818249014142
648106	ASPEN ROM KNEE, XXL	818249014159
648111	ASPEN ROM KNEE, UNIV	818249014098
652001	Aspen Ci Knee, S, Left	818249014432
652002	Aspen Ci Knee, M, Left	818249014456
652003	Aspen Ci Knee, L, Left	818249014470
652004	Aspen Ci Knee, XL, Left	818249014494
652006	Aspen Ci Knee, S, Right	818249014449
652007	Aspen Ci Knee, M, Right	818249014463
652008	Aspen Ci Knee, L, Right	818249014487
652009	Aspen Ci Knee, XL, Right	818249014500
652120	ASPEN CI KNEE, STRAP ACCY. KIT - S	818249014517
652121	ASPEN CI KNEE, STRAP ACCY. KIT - M	818249014524
652122	ASPEN CI KNEE, STRAP ACCY. KIT - L	818249014531
652123	ASPEN CI KNEE, STRAP ACCY. KIT - XL	818249014548
652125	ASPEN CI KNEE, LINER ACCY. KIT - S	818249014555
652126	ASPEN CI KNEE, LINER ACCY. KIT - M	818249014562
652127	ASPEN CI KNEE, LINER ACCY. KIT - L	818249014579
652128	ASPEN CI KNEE, LINER ACCY. KIT - XL	818249014586
652130	ASPEN CI KNEE, EXTENSION/FLEXION STOP FRAME	818249014593
651130	QUICK RELEASE BUCKLE KIT	818249013985