

## 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)

#### OA KNEE

Product Name	Product Code / Catalog Number	Basic UDI-DI
Aspen OA Knee+ Extended Strap Set Strap Accessory Kit Liner Accessory Kit	Extension/Flexion Stop Frame Varus/Valgus Adjustment Key Aspen Suspension Wrap Aspen OA Knee Wrap	See attached list  081824901OAKNEE8Q

#### 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:** 16 January 2021

<b>REF</b>	<b>Description</b>	<b>UDI</b>
651011	ASPEN OA KNEE+, LEFT	818249013992
651012	ASPEN OA KNEE+, RIGHT	818249014005
651124	EXTENDED STRAP SET	818249014012
651125	STRAP ACCY KIT	818249014029
651126	LINER ACCY KIT, LEFT	818249014036
651127	LINER ACCY KIT, RIGHT	818249014043
651128	EXT/FLEXION STOP FRAME	818249014050
651129	VARUS/VALGUS ADJ KEY	818249014067
651111	ASPEN SUSPENSION WRAP	818249014234
651021	ASPEN OA KNEE WRAP, S (LEFT)	818249014333
651022	ASPEN OA KNEE WRAP, M (LEFT)	818249014340
651023	ASPEN OA KNEE WRAP, L (LEFT)	818249014357
651024	ASPEN OA KNEE WRAP, XL (LEFT)	818249014364
651025	ASPEN OA KNEE WRAP, XXL (LEFT)	818249014371
651026	ASPEN OA KNEE WRAP, S (RIGHT)	818249014388
651027	ASPEN OA KNEE WRAP, M (RIGHT)	818249014395
651028	ASPEN OA KNEE WRAP, L (RIGHT)	818249014401
651029	ASPEN OA KNEE WRAP, XL (RIGHT)	818249014418
651030	ASPEN OA KNEE WRAP, XXL (RIGHT)	818249014425