



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)		
WRIST		
Product Name	Product Code / Catalog Number	Basic UDI-DI
Aspen Hinged Wrist	See attached list	081824901WRISTFN
Intended Purpose		
To provide sagittal and coronal plane stabilization of the wrist.		

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
645011	ASPEN HINGED WRIST, UNIV	818249014241