AVANOS

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EU Declaration of Conformity

Legal Manufacturer:

AVANOS Medical, Inc.
5405 Windward Parkway
Alpharetta, GA 30004
United States of America
Single Registration Number (SRN): US-MF-000016181

Authorised Representative:

Avanos Medical Belgium BV
Leonardo Da Vincilaan 1
1930 Zaventem
Belgium
Single Registration Number (SRN): BE-AR-000002191

GMDN Code and Term: 60607, Circulating-fluid thermal/compression therapy system control unit

EMDN Code and Term: Z12060 Physiotherapy and Rehabilitation Instruments
Z120607 Pneumatic Compression Units

Identification of Device(s):

Product Code(s)	Trade Name and Description	Product Family	Basic UDI-DI:	Risk Class	Annex VIII Classification Rule	Start Date of EU MDR CE Mark
550500-53	GRPRO* 2.1 SYSTEM OUS	Game Ready GRPro 2.1 Control Unit	0193493GRPR089243W	IIa	Annex VIII, Rule 9	16-Oct-2024
550500-53-DM	GRPRO* 2.1 SYSTEM – OUS DEMO	Game Ready GRPro 2.1 Control Unit	0193493GRPR089243W	IIa	Annex VIII, Rule 9	16-Oct-2024
550500-63	GRPRO* 2.1 SYSTEM OUS MEDICAL	Game Ready GRPro 2.1 Control Unit	0193493GRPR089243W	IIa	Annex VIII, Rule 9	16-Oct-2024
550500-63-DM	GRPRO* 2.1 SYSTEM – OUS DEMO MEDICAL	Game Ready GRPro 2.1 Control Unit	0193493GRPR089243W	IIa	Annex VIII, Rule 9	16-Oct-2024

Intended Purpose:	The GRPro* 2.1 System is an advancement on the standard treatment protocol referred to as RICE (Rest, Ice, Compression, and Elevation). The RICE protocol is standard treatment for both acute injuries as well as post-surgical pain. The GRPro* 2.1 System advances the RICE protocol by defining unique treatment algorithms of cryotherapy, with intermittent compression that can be fine-tuned by a healthcare professional. The GRPro 2.1 System combines cold and compression therapies. It is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain for which cold and compression are indicated. It is intended to be used by or on the order of licensed healthcare professionals in hospitals, outpatient clinics, athletic training settings, or home settings.
Conformity Assessment Procedure:	Annex IX Assessment of Quality Management System and Technical Documentation
Notified Body:	BSI Group The Netherlands B.V. Notified Body Identification Number: 2797
EU Certificate(s) Issued:	MDR 760399

This EU Declaration of Conformity is issued according to Annex IV under the sole responsibility of AVANOS Medical, Inc. The device(s) contained within this declaration is/are in conformance with EU 2017/745Medical Device Regulations.

Identification of the person authorized to sign for and on behalf of Avanos Medical, Inc.:

Signature: 

Name: Pamela Campo

Title: Associate Director, Regulatory Affairs

Date: 17-Oct-2024

(DD-MMM-YYYY)

Place of Issue: AVANOS Medical, Inc.
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