

EU Declaration of Conformity

Legal Manufacturer:



AVANOS Medical, Inc.  
5405 Windward Parkway  
Alpharetta, GA 30004  
United States of America  
Single Registration Number (SRN): UM-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
650500	Game Ready* Med4 Elite Control Unit	Game Ready Med4 Elite	0193493GRME08925UZ	Ila	Annex VIII, Rule 9	26-Aug-2024
650550-DM	Game Ready* Med4 Elite Control Unit - Demo	Game Ready Med4 Elite	0193493GRME08925UZ	Ila	Annex VIII, Rule 9	26-Aug-2024
650550-LN	Game Ready* Med4 Elite Control Unit - Loaner	Game Ready Med4 Elite	0193493GRME08925UZ	Ila	Annex VIII, Rule 9	26-Aug-2024
650500-EN01	Game Ready* Med4 Elite System North America, English	Game Ready Med4 Elite	0193493GRME08925UZ	Ila	Annex VIII, Rule 9	26-Aug-2024
650500-EX01	Game Ready* Med4 Elite System North America, Spanish	Game Ready Med4 Elite	0193493GRME08925UZ	Ila	Annex VIII, Rule 9	26-Aug-2024
650500-FR01	Game Ready* Med4 Elite System North America, French	Game Ready Med4 Elite	0193493GRME08925UZ	Ila	Annex VIII, Rule 9	26-Aug-2024
650500-EN02	Game Ready* Med4 Elite System EU, English	Game Ready Med4 Elite	0193493GRME08925UZ	Ila	Annex VIII, Rule 9	26-Aug-2024

650500-FR02	Game Ready* Med4 Elite System EU, French	Game Ready Med4 Elite	0193493GRME0 8925UZ	Ila	Annex VIII, Rule 9	26-Aug-2024
650500-DE02	Game Ready* Med4 Elite System EU, German	Game Ready Med4 Elite	0193493GRME0 8925UZ	Ila	Annex VIII, Rule 9	26-Aug-2024
650500-EX02	Game Ready* Med4 Elite System EU, Spanish	Game Ready Med4 Elite	0193493GRME0 8925UZ	Ila	Annex VIII, Rule 9	26-Aug-2024
650500-EN03	Game Ready* Med4 Elite System UK, English	Game Ready Med4 Elite	0193493GRME0 8925UZ	Ila	Annex VIII, Rule 9	26-Aug-2024
650500-IT04	Game Ready* Med4 Elite System Italy, Italian	Game Ready Med4 Elite	0193493GRME0 8925UZ	Ila	Annex VIII, Rule 9	26-Aug-2024
650500-EX04	Game Ready* Med4 Elite System Italy, Spanish	Game Ready Med4 Elite	0193493GRME0 8925UZ	Ila	Annex VIII, Rule 9	26-Aug-2024
650500-EN06	Game Ready* Med4 Elite System Switzerland, English	Game Ready Med4 Elite	0193493GRME0 8925UZ	Ila	Annex VIII, Rule 9	26-Aug-2024
650500-FR06	Game Ready* Med4 Elite System Switzerland, French	Game Ready Med4 Elite	0193493GRME0 8925UZ	Ila	Annex VIII, Rule 9	26-Aug-2024
650500-DE06	Game Ready* Med4 Elite System Switzerland, German	Game Ready Med4 Elite	0193493GRME0 8925UZ	Ila	Annex VIII, Rule 9	26-Aug-2024
650500-IT06	Game Ready* Med4 Elite System Switzerland, Italian	Game Ready Med4 Elite	0193493GRME0 8925UZ	Ila	Annex VIII, Rule 9	26-Aug-2024
650500-EN10	Game Ready* Med4 Elite System Denmark, English	Game Ready Med4 Elite	0193493GRME0 8925UZ	Ila	Annex VIII, Rule 9	26-Aug-2024
650500-EN11	Game Ready* Med4 Elite System Israel, English	Game Ready Med4 Elite	0193493GRME0 8925UZ	Ila	Annex VIII, Rule 9	26-Aug-2024

**Intended Purpose:**

The Med4 Elite\* System combines cold, heat, contrast, and compression therapies. It is intended to treat postsurgical and acute injuries to reduce edema, swelling and pain for which cold and compression are indicated. It is intended to treat post traumatic and post surgical medical and/or surgical conditions for which localized thermal therapy (hot or cold or contrast) are indicated. It is intended to be used by, or on the order of, licensed healthcare professionals in rehabilitation facilities, outpatient clinics, and athletic training 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 (Full Quality Certificate)

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 2017/745 Medical Device Regulations.

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

Signature: \_\_\_\_\_

Name:   Liane Miller  

Title: Senior Director, Regulatory Affairs

Date: \_\_\_\_\_  
(DD-MMM-YYYY)

Place of Issue: AVANOS Medical, Inc.  
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