

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	Model/number
WaffleGrip Trendelenburg Positioning System	See Page 2

MANUFACTURER		
Name of company	Address	Representative
Augustine Temperature Management LLC	Corporate 6581 City West Parkway Eden Prairie, MN 55344 USA Manufacturing 7656 W. 78 th St. Minneapolis, MN 55439 USA	Ivona Domnisoru Quality & Regulatory Representative 1.952.465.3851 phone 1.952.465.3501 fax idomnisoru@augurg.com
SRN	US-MF-000020611	

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	(31) (0) 70 345-8570 europe@emergogroup.com
SRN	NL-AR-000000116	

CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class I Rule 1, Annex VIII	Annex IX of EU Medical Device Regulation 2017/745	ISO 13485:2016 Certificate: FM 504729 MDSAP Certificate: 715042 EU Medical Device Regulation 2017/745
Basic UDI	0855913001WGTPS7C	

Augustine Temperature Management declares that the above-mentioned products meet the provision of the EU Medical Device Regulation 2017/745 as transposed in the national laws of the Member States. The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

COMPANY REPRESENTATIVE: Ivona Domnisoru

TITLE: Quality & Regulatory Representative

PLACE: Eden Prairie , Minnesota, USA

SIGNATURE:



DATE: 01/12/2023



Augustine Temperature Management LLC Product Listing for Declaration of Conformity

WaffleGrip Trendelenburg Positioning System Product List	
Catalog Number	Description
A300	WaffleGrip Trendelenburg Positioning Kit
A301	WaffleGrip™ Trendelenburg Positioning Kit + BackSaver™ Slide Sheet