Danmar Products
Equipping people. Enhancing lives.

Declaration of Conformity for Class I Devices

According to MDR 2017/745

Manufacturer:

Danmar Products, Inc.
221 Jackson Industrial Dr.
Ann Arbor, MI 48103 - USA

Authorized Representative:

HEA Medical AB
Norra Ågatan 10, 416 64
Göteborg, Sweden

We, the manufacturer, declare and ensure with sole responsibility that the below mentioned Medical Device(s) meet(s) the provisions of the Medical Device Regulation 2017/745/EU (MDR) which apply to them. The device(s) covered by the present declaration are in conformity with the MDR 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

Product and Trade Name	Product Code(s)	Basic UDI-DI
Head Supports	6809	0819076026809YJ
	6810	0819076026810Y3
	6815	0819076026815YD
	6826	0819076026826YJ
	6828	0819076026828YN
	6833	0819076026833YF

Intended Purpose of the Device: Supportive positioning aid for head support.
Risk Class: Class I

Signed By:

Hidie Bowman

Hidie Bowman, CEO of Danmar Products, Inc
Place and Date of Issue: Ann Arbor, MI, USA – March 23, 2022

(800) 783-1998
fax: (734) 761-8977
www.danmarproducts.com