

Good Manufacturing Practices Statement



Effective Date: November 11, 2024

This is to certify the following:

TheraTogs, Inc.

Product(s) Name:

TheraTogs Wunzi Infant System	UDI: 8100494GWZDR
TheraTogs Posture & Torso Alignment (PTA) System	UDI: 8100494GPTAYY
TheraTogs Full Body System	UDI: 8100494GFBAN
TheraTogs Lower Extremity System	UDI: 8100494GLEBE

We guarantee the Class I Exempt products manufactured at TheraTogs, Inc. are in compliance with the applicable elements of the Good Manufacturing Practices (GMP) standards, and are in compliance with Medical Devices Regulation (EU) 2017/745.

The above-mentioned facility and controls used for the manufacturing and distribution of TheraTogs products are in conformity with applicable Good Manufacturing Practices, in accordance with section 211, title 21, Code of Federal Food, Drugs and Cosmetics Act, and the Amendments thereto; and in conformance with Medical Devices Regulation (EU) 2017/745.

We hereby certify the above statements to be true and correct to the best of our knowledge and belief.

Respectfully submitted,

Lee Taylor
Chief Executive Officer / Chairman of the Board
TheraTogs, Inc
305 Society Drive STE C-3
Telluride, CO 81435 | USA
ltaylor@theratogs.com
+1 (970) 239-0104