

Declaration of Conformity

Manufacturer:

Leggero, LLC
2802 S. Water Street 
Burnet, Tx USA 78611
Ph: +1 (512) 756-4700

**EC Authorized Representative:**

MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany
Tel: +49 511 6262 8630+



We, Leggero, LLC, declare that the Trak is in conformity with the applicable provisions of 2017/745 European Union (EU) Medical device Regulation of the European Parliament and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity, ISO 14971:2007, Application of Risk Management to Medical Devices, and in have been found to be in compliance with Dimensional, performance, static, impact and fatigue tests according to ISO: 7176-1:1999, 7176-5:2008, 7176-7:1998, 7176-8:1998, 7176-13:1989, 7176-16:2012, 7176-22:2000.

Trak Part Numbers: 3002-1001, 3002-1002, 3002-1003, 3002-1004.

Class of Device: Class 1 medical device. Rule 1.

SRN: DE-AR-000005430

Basic UDI-DI #: ++B5143002VQ

Description of Device: Rehab pushchairs and pediatric positioning systems are appropriate for children who are limited to a seated position and require mobility and positioning assistance. Individuals who need such assistance can have a wide variety of diagnosis limiting their ability to achieve mobility without such a system.

"We explicitly designate MDSS GmbH, Schiffgraben 41, 30175 Hannover, Germany to act as our sole Authorized Representative in the European Union for the above indicated products."

Place of Issue:

Leggero, LLC
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Burnet, Tx USA 78611

Attestation made by the following Leggero LLC Personnel:

Gabriela Romero Cedillo

(Name)
Authorized Representative

Gabriela R. Cedillo

General Manager, Leggero LLC

7/5/2021

Date of Issue