



Declaration of Conformity

Manufacturer:

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EC Authorized Representative:

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We, Leggero, LLC, declare that the ENZO is in conformity with the applicable provisions of Council Directive 93/42/EEC concerning Medical devices, 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, 7176-22:2000. Approved by the 510(k) Premarket Notification and its testing directives.

Enzo Wheelchair Part Numbers: 3101-0200, 3101-0002, 3101-0201, 3101-0001.

Class of Device: Class 1 medical device.

Description of Device:

The Enzo pediatric wheelchair is intended for medical purposes to provide mobility to persons restricted to a sitting position.

Gabriela Romero Cedillo

(Name)
Authorized Representative

Gabriela R. Cedillo

General Manager, Leggero LLC

9/17/2019

Date