



EU Declaration of Conformity

Manufacturer	R82 A/S Parallelvej 3 DK-8751 Gedved Denmark Phone: +45 7965 5888 www.etac.com
SRN	DK-MF-000000772
Statement	<p>This declaration of conformity is issued under the sole responsibility of the manufacturer.</p> <p>The device(s) covered by this declaration of conformity is/are in conformity with EU Regulation 2017/745 on medical devices.</p>
Basic UDI-DI	57072920536033A
Device description	Device family: Standing
EMDN	Y050202
Intended Purpose	<p>The family of R82 Standing devices consist of assistive devices intended for the alleviation of or compensation for a functional impairment due to an injury or disability. The devices are designed for an individual lacking the ability to maintain the standing position without the use of an assistive device.</p> <p>Addax is an assistive device designed to support infants, children and adolescents (and adults who fit within the dimensions of the device) to perform supported standing. The device is intended for users where limited leg and trunk control makes standing upright difficult or impossible without support. The device has adjustable features in the frame and accessories to accommodate for the individual needs of the user.</p>
Device name(s)	Addax
Parts covered in this declaration	Separate list available upon request.
Risk class of the device	Class I, Rule 1
Harmonized/Established Standards	Separate list available upon request

Place Gedved, Denmark
Date of issue 2025-12-12
Name and function QA/RA Manager, Claus Riis

C. Riis

Signature, on behalf of Manufacturer