



UK DECLARATION OF CONFORMITY

In accordance with UK Government Guidance

Manufacturer	R82 A/S Parallelevæj 3 DK-8751 Gedved Denmark Phone: +45 7965588 www.etac.com	UK Responsible Person	Etac Ltd Unit 60, Hartlebury Trading Estate, Hartlebury, Kidderminster, DY10 4JD Email enquiries.uk@etac.com Web www.etac.com/uk Phone +44 (0)121 561 2222
Statement	This declaration of conformity is issued under the sole responsibility of the manufacturer. The device(s) covered by this declaration of conformity is/are in conformity with UK MDR 2002 (Medical Device Regulations 2002)		
Basic UDI-DI	57072920536033A		
GMDN	61700		
Intended purpose	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.		
	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.		
Device name	Addax		
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	Claus Riis - QA & RA Manager		

Signature, on behalf of manufacturer