



## **UK Declaration of Conformity**

## In accordance with UK Government Guidance

Manufacturer

R82 A/S

Parallelvej 3 DK-8751 Gedved

Denmark

Phone: +45 7965 5888

www.etac.com

Statement

This declaration of conformity is issued under the sole responsibility

of the manufacturer.

The device(s) covered by the present declaration is/are in conformity

with UK MDR 2002 (Medical Device Regulations 2002).

Device name

Combi Frame:x

Intended purpose

Frame for seating systems for persons with disabilities

**GMDN** 

41512

Risk class of the device

Class I, rule 1

**Common specifications** 

Separate list available upon request

**UK Responsible Person** 

Etac Ltd

Unit 60, Hartlebury Trading Estate, Hartlebury

Kidderminster, DY10 4JD

Email: <a href="mailto:enquiries.uk@etac.com">enquiries.uk@etac.com</a> Website: <a href="mailto:www.etac.com/uk">www.etac.com/uk</a> Phone: +44 (0)121 561 2222

Place

Gedved, Denmark

Date of issue

2023-11-21

Name and function

Dianna Hessellund Jensen, Director QA/RA

Signature, on behalf of manufacturer