



UK DECLARATION OF CONFORMITY

In accordance with UK Government Guidance

Manufacturer

Etac Immedia A/S

UK Responsible Person

Etac Ltd

Parallelvej 3 DK-8751 Gedved

Unit 60, Hartlebury Trading Estate, Hartlebury, Kidderminster, DY10

4JD

www.etac.com

Denmark

Email enquiries.uk@etac.com

Web <u>www.etac.com/uk</u> 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

57080125002MG

Device description

Support

GMDN

40538

Intended purpose

The assistive device is intended for alleviation of, or compensation for, a functional

impairment due to an injury or disability. The device is designed for an individual lacking the

ability to transfer or position themselves due to reduced mobility or physical strength.

Device name(s)

SupportBelt

Risk class of the device

Class I, rule I

Harmonized/Established

Standards

eu

Separate list available upon request

Place

Gedved, Denmark

Date of issue

15. January 2024

Name and function

Michael Bruun, Senior Vice President

Signature, on behalf of Etac Immedia A/S