



## EC Declaration of Conformity Certificate

To whom it may concern

Struer, Denmark, June 2025

We, **KNOP Elektronik A/S**, hereby declare on our own responsibility as the manufacturer, that the following variants (see the table below) of the Medical Device: with the following intended use:

The medical device consists of a combination of products to call for assistance used for disabled people as e.g., walking impaired people, that need help for going to the bathroom. The senders are activated by a sound or by pressure. The receiver is surveilled by health care personnel. The combination system is not designed for critically or mentally ill persons.

Meet all, of the requirements of the:

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, with amendments (MDR).

<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	IDT125: With internal antenna IDT130: External loop antenna IDT131: Outdoor FC121: External antenna for IDT125
<b>Product description</b>	Position transmitter, other products will pick up the position when passing it. Used for locating a transmitter or receiver and passing this location to an assistance transmission.
<b>Serial numbers</b>	S/N located on product.
<b>Basic UDI-DI</b>	NA
<b>Classification according to MDR</b>	NA
<b>SRN: Single Registration Number</b>	NA
<b>Route of conformity for all variants of the product</b>	Annex I General safety and performance requirements. Annex II Technical documentation. Annex III Technical documentation on post-market surveillance.
<b>Other relevant legislation, and applicable harmonized standards, and normative documents.</b>	EN 301 498-1 V2.2.3 EN 301 489-3 V3.1.1 EN 50130-4:2011 + 2014 EN 300 220-1 V3.1.1 EN 300 220-2 V3.1.1 EN 300 220-3-1 V2.1.1 EN 300 330 V2.1.1 EN 60601-1-2:2015 EN 60601-1-2:2014 EN 62368-1:2020 EN 50581:2012 ETSI EN 300 330 V2.1.1 REACH Directive 1907/2006/EU RoHS Directive 2011/65/EU ISO 14971:2019
<b>Manufacturer:</b> <b>Telephone:</b> <b>Owner/ Position:</b> <b>Company No.:</b>	<b>KNOP ELEKTRONIK A/S</b> +45 97 84 04 44 CEO Jan Knop DK28305249
<b>Date</b>	<b>Signature:</b>  CEO Jan Knop

10-06-2025