



## EC Declaration of Conformity Certificate

To whom it may concern


Struer, Denmark, Juni, 2022

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:

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<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	CT901 Controller
<b>Product description</b>	The CT901 is a controller for Knop products.
<b>Serial numbers</b>	Valid from S/N: 1XXXXX, S/N located on product.
<b>Basic UDI-DI</b>	574400285CT9013M
<b>Classification according to MDR</b>	Class I, Rule 1
<b>SRN: Single Registration Number</b>	DK-MF-000025631
<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 60601-1-2:2015 EN 60601-1-2:2014 EN 62368-1:2020 EN 50581:2012 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
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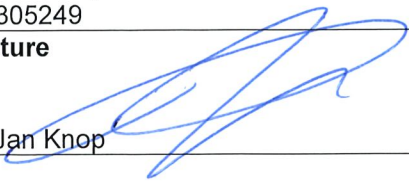
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<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	CT901BED Bed monitor
<b>Product description</b>	The CT901BED is a specialized controller for client/bed/light.
<b>Serial numbers</b>	Valid from S/N: 1XXXXXX, S/N located on product.
<b>Basic UDI-DI</b>	574400285CT9013M
<b>Classification according to MDR</b>	Class I, Rule 1
<b>SRN: Single Registration Number</b>	DK-MF-000025631
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<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	KK101: Ping-Pong switch (with cable)
<b>Product description</b>	Personal activator for a patient/client with special needs for calling assistance. Activation by pushing a ping-pong ball.
<b>Serial numbers</b>	Valid from S/N: 1XXXXX, S/N located on product.
<b>Basic UDI-DI</b>	574400285KK9014E
<b>Classification according to MDR</b>	Class I, Rule 1
<b>SRN: Single Registration Number</b>	DK-MF-000025631
<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.
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<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	KK901P: Ping-Pong switch (with position detector) KK901: Ping-Pong switch (without position detector)
<b>Product description</b>	Personal transmitter for a patient/client with special needs for calling assistance. Activation by pushing a ping-pong ball.
<b>Serial numbers</b>	Valid from S/N: 1XXXXX, S/N located on product.
<b>Basic UDI-DI</b>	574400285KK9014E
<b>Classification according to MDR</b>	Class I, Rule 1
<b>SRN: Single Registration Number</b>	DK-MF-000025631
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<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	LAK901: Sound to alarm MI901: External microphone
<b>Product description</b>	Transmitter for a patient/client with special needs. The transmission is activated when the patient/client makes a noise/sound for calling assistance.
<b>Serial numbers</b>	Valid from SN: 1XXXXX, S/N located on product.
<b>Basic UDI-DI</b>	574400285LAK9012T
<b>Classification according to MDR</b>	Class I, Rule 1
<b>SRN: Single Registration Number</b>	DK-MF-000025631
<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.
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<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	LS901 Light Slave
<b>Product description</b>	The light slave will light up the room or walk pass if a transmitter has been activated by patient/client to avoid patient/client falling.
<b>Serial numbers</b>	Valid from S/N: 1XXXXXX, S/N located on product.
<b>Basic UDI-DI</b>	574400285LS9016H
<b>Classification according to MDR</b>	Class I, Rule 1
<b>SRN: Single Registration Number</b>	DK-MF-000025631
<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.
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<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	MR902 Master Repeater
<b>Product description</b>	The MR902 is a master controller in repeater system for Knop products. Repeater system consist of a MR902 and several RP902 where each RP902 extents the broadcast range of the transmitters.
<b>Serial numbers</b>	Valid from S/N: 1XXXXX, S/N located on product.
<b>Basic UDI-DI</b>	574400285MR9026P
<b>Classification according to MDR</b>	Class I, Rule 1
<b>SRN: Single Registration Number</b>	DK-MF-000025631
<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 60601-1-2:2015 EN 60601-1-2:2014 EN 62368-1:2020 EN 50581:2012 REACH Directive 1907/2006/EU RoHS Directive 2011/65/EU ISO 14971:2019
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<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	PIR900 Motion detect/Bed guard
<b>Product description</b>	Personal transmitter for a patient/client with special needs for calling assistance.
<b>Serial numbers</b>	Valid from S/N: 1XXXXX, S/N located on product.
<b>Basic UDI-DI</b>	574400285PIR9008N
<b>Classification according to MDR</b>	Class I, Rule 1
<b>SRN: Single Registration Number</b>	DK-MF-000025631
<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.
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<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	POS901: With internal antenna POS901L: External loop antenna POS901S: External antenna for POS901
<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>	Valid from S/N: 1XXXXX, S/N located on product.
<b>Basic UDI-DI</b>	574400285POS901AZ
<b>Classification according to MDR</b>	Class I, Rule 1
<b>SRN: Single Registration Number</b>	DK-MF-000025631
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<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	RP901 Repeater
<b>Product description</b>	RP901 extends the broadcast range of transmitters in a standalone system.
<b>Serial numbers</b>	Valid from S/N: 1XXXXX, S/N located on product.
<b>Basic UDI-DI</b>	574400285RP9017W
<b>Classification according to MDR</b>	Class I, Rule 1
<b>SRN: Single Registration Number</b>	DK-MF-000025631
<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.
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<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	RP902 Repeater
<b>Product description</b>	RP902 extends the broadcast range of transmitters either in system or standalone. Typically, a repeater system consists of one MR902 (master) and several RP902.
<b>Serial numbers</b>	Valid from S/N: 1XXXXXX, S/N located on product.
<b>Basic UDI-DI</b>	574400285RP9027Y
<b>Classification according to MDR</b>	Class I, Rule 1
<b>SRN: Single Registration Number</b>	DK-MF-000025631
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<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	PU101: Blow switch (with cable)
<b>Product description</b>	Personal switch for a patient/client with special needs for calling assistance. Activation by blowing into the product.
<b>Serial numbers</b>	Valid from S/N: 1XXXXX, S/N located on product.
<b>Basic UDI-DI</b>	574400285PU9018B
<b>Classification according to MDR</b>	Class I, Rule 1
<b>SRN: Single Registration Number</b>	DK-MF-000025631
<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 60601-1-2:2015 EN 60601-1-2:2014 EN 62368-1:2020 EN 50581:2012 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 





## EC Declaration of Conformity Certificate

To whom it may concern

Struer, Denmark, Juni, 2022

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with the following intended use:

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Meet all, of the requirements of the:

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<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	PU901P: Blow switch (with position detector) PU901: Blow switch (without position detector)
<b>Product description</b>	Personal transmitter for a patient/client with special needs for calling assistance. Activation by blowing into the product.
<b>Serial numbers</b>	Valid from S/N: 1XXXXX, S/N located on product.
<b>Basic UDI-DI</b>	574400285PU9018B
<b>Classification according to MDR</b>	Class I, Rule 1
<b>SRN: Single Registration Number</b>	DK-MF-000025631
<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 60601-1-2:2015 EN 60601-1-2:2014 EN 62368-1:2020 EN 50581:2012 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
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Issue	Comments
Product name	RTX901D 1-Channel transmitter/receiver
Product description	The transmitter for a patient/client with special needs. The transmission is activated from an external input to call for assistance. Receiver activates a relay output for external use.
Serial numbers	Valid from SN: 1xxxxx, S/N located on product
Basic UDI-DI	574400285RTX901DMG
Classification according to MDR	Class I, Rule 1
SRN: Single Registration Number	DK-MF-000025631
Route of conformity for all variants of the product	Annex I: General safety and performance requirements. Annex II: Technical documentation. Annex III: Technical documentation on post-market surveillance.
Other relevant legislation, and applicable harmonized standards, and normative documents.	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 60601-1-2:2015 EN 60601-1-2:2014 EN 62368-1:2020 EN 50581:2012 REACH Directive 1907/2006/EU RoHS Directive 2011/65/EU ISO 14971:2019
Manufacturer: Telephone: Owner/Position: Company No.:	<b>KNOP ELEKTRONIK A/S</b> +45 97 84 04 44 CEO Jan Knop DK28305249
Date	Signature  CEO Jan Knop





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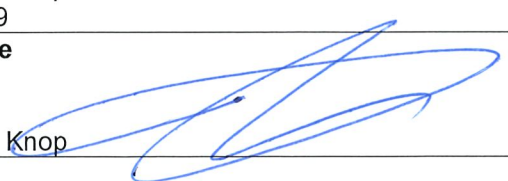
Struer, Denmark, Juni, 2022

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<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	RX901B: Receiver with LCD RX901B-4: 4-ch Receiver with LCD
<b>Product description</b>	Programmable receiver. The product will receive the assistance request from the transmitters programmed into the receiver.
<b>Serial numbers</b>	Valid from S/N: 1XXXXX, S/N located on product.
<b>Basic UDI-DI</b>	574400285RX901B95
<b>Classification according to MDR</b>	Class I, Rule 1
<b>SRN: Single Registration Number</b>	DK-MF-000025631
<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 60601-1-2:2015 EN 60601-1-2:2014 EN 62368-1:2020 EN 50581:2012 REACH Directive 1907/2006/EU RoHS Directive 2011/65/EU ISO 14971:2019
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<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	RX901C Receiver with 4 relay outputs.
<b>Product description</b>	The receiver can be programmed to receive 4 different transmitters and activate a relay output according.
<b>Serial numbers</b>	Valid from SN: 1XXXXX, S/N located on product
<b>Basic UDI-DI</b>	574400285RX901C97
<b>Classification according to MDR</b>	Class I, Rule 1
<b>SRN: Single Registration Number</b>	DK-MF-000025631
<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 60601-1-2:2015 EN 60601-1-2:2014 EN 62368-1:2020 EN 50581:2012 REACH Directive 1907/2006/EU RoHS Directive 2011/65/EU ISO 14971:2019
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<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	TR303417HF & TR303410HF: Transmitter with position detector.
<b>Product description</b>	Personal transmitter for a patient/client with special needs for calling assistance. Activation is via pressure mat TR303417HF or TR303410HF.
<b>Serial numbers</b>	Valid from S/N: 1XXXXX, S/N located on product.
<b>Basic UDI-DI</b>	574400285TR90192
<b>Classification according to MDR</b>	Class I, Rule 1
<b>SRN: Single Registration Number</b>	DK-MF-000025631
<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 60601-1-2:2015 EN 60601-1-2:2014 EN 62368-1:2020 EN 50581:2012 REACH Directive 1907/2006/EU RoHS Directive 2011/65/EU ISO 14971:2019
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<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	TX901 Alarm transmitter/Door Guard
<b>Product description</b>	Personal transmitter for a patient/client with special needs for calling assistance. Different activation methods apply.
<b>Serial numbers</b>	Valid from S/N: 1XXXXX, S/N located on product.
<b>Basic UDI-DI</b>	574400285TX901AC
<b>Classification according to MDR</b>	Class I, Rule 1
<b>SRN: Single Registration Number</b>	DK-MF-000025631
<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 60601-1-2:2015 EN 60601-1-2:2014 EN 62368-1:2020 EN 50581:2012 REACH Directive 1907/2006/EU RoHS Directive 2011/65/EU ISO 14971:2019
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<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	TX901A: Bracelet transmitter (without position detector) TX901A-T: Necklace transmitter large push button TX901A-H: Necklace transmitter TX901AP: Bracelet transmitter (with position detector)
<b>Product description</b>	Personal transmitter for a patient/client with special needs for calling assistance. Activation methods according to the product.
<b>Serial numbers</b>	Valid from S/N: 1XXXXX, S/N located on product.
<b>Basic UDI-DI</b>	574400285TX901A9V
<b>Classification according to MDR</b>	Class I, Rule 1
<b>SRN: Single Registration Number</b>	DK-MF-000025631
<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 60601-1-2:2015 EN 60601-1-2:2014 EN 62368-1:2020 EN 50581:2012 REACH Directive 1907/2006/EU RoHS Directive 2011/65/EU ISO 14971:2019
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<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	TX901D 1-channel transmitter
<b>Product description</b>	Transmitter for a patient/client with special needs. The transmission is activated from an external input to call for assistance.
<b>Serial numbers</b>	Valid from SN: 1xxxxx, S/N located on product.
<b>Basic UDI-DI</b>	574400285TX901DA3
<b>Classification according to MDR</b>	Class I, Rule 1
<b>SRN: Single Registration Number</b>	DK-MF-000025631
<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 60601-1-2:2015 EN 60601-1-2:2014 EN 62368-1:2020 EN 50581:2012 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