



## 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:

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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>	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
<b>Date:</b> <i>01/10/2024</i>	<b>Signature:</b>  CEO Jan Knop



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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>	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.
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<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	EPI900 Seizure alarm
<b>Product description</b>	Transmitter for a patient/client with special needs.
<b>Serial numbers</b>	S/N located on product.
<b>Basic UDI-DI</b>	574400285EPI9004M
<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>	KK100: 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>	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>	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>	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>	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>	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 extends the broadcast range of the transmitters.
<b>Serial numbers</b>	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.
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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>	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
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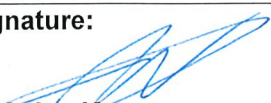
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<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	POS901: With internal antenna POS901L: External loop antenna POS901S: External antenna for POS901
<b>Product description</b>	Position transmitter, other products will pick up the position when passing it. Used for locating a transmitter or receiver and passing this location to an assistance transmission.
<b>Serial numbers</b>	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>	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>	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
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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>	S/N located on product.
<b>Basic UDI-DI</b>	574400285PU9018B
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<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: Telephone: Owner/ Position: Company No.:</b>	<b>KNOP ELEKTRONIK A/S</b> +45 97 84 04 44 CEO Jan Knop DK28305249
<b>Date:</b>  01/10/2024	<b>Signature:</b>  CEO Jan Knop



## EC Declaration of Conformity Certificate

To whom it may concern


Struer, Denmark, Juni, 2022

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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>	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>	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
<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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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	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
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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>	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>	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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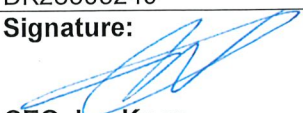
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<b>Issue:</b>	<b>Comments:</b>
<b>Product name</b>	TR303417HF & TR303410HF: Transmitter with position detector.
<b>Product description</b>	Personal transmitter for a patient/client with special needs for calling assistance. Activation is via pressure mat TR303417HF or TR303410HF.
<b>Serial numbers</b>	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.
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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>	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>	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.
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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>	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
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