

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:

Issue:	Comments:		
Product name	CT901 Controller		
Product description	The CT901 is a controller for Knop products.		
Serial numbers	Valid from S/N: 1XXXXX, S/N located on product.		
Basic UDI-DI	574400285CT9013M		
Classification according to MDR	Class I, Rule 1		
SRN: Single Registration Number	DK-MF-000025631		
Route of conformity for all	Annex I General safety and performance requirements.		
variants of the product	Annex II Technical documentation.		
· ·	Annex III Technical documentation on post-market		
	surveillance.		
Other relevant legislation, and	EN 301 498-1 V2.2.3		
applicable harmonized	EN 301 489-3 V3.1.1		
standards, and normative	EN 50130-4:2011 + 2014		
documents.	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:	KNOP ELEKTRONIK A/S		
Telephone:	+45 97 84 04 44		
Owner/ Position:	CEO Jan Knop		
Company No.:	DK28305249		
Date	Signature		
	CEO lan Kaan		
	CEO Jan Knop		



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Meet all, of the requirements of the:

Issue:	Comments:		
Product name	CT901BED Bed monitor		
Product description	The CT901BED is a specialized controller for client/bed/light.		
Serial numbers	Valid from S/N: 1XXXXX, S/N located on product.		
Basic UDI-DI	574400285CT9013M		
Classification according to MDR	Class I, Rule 1		
SRN: Single Registration Number	DK-MF-000025631		
Route of conformity for all	Annex I General safety and performance requirements.		
variants of the product	Annex II Technical documentation.		
	Annex III Technical documentation on post-market		
	surveillance.		
Other relevant legislation, and	EN 301 498-1 V2.2.3		
applicable harmonized	EN 301 489-3 V3.1.1		
standards, and normative	EN 50130-4:2011 + 2014		
documents.	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		
a a	EN 50581:2012		
	REACH Directive 1907/2006/EU		
	RoHS Directive 2011/65/EU		
BH f f f	ISO 14971:2019		
Manufacturer:	KNOP ELEKTRONIK A/S +45 97 84 04 44		
Telephone:			
Owner/ Position:	CEO Jan Knop DK28305249		
Company No.:	Signature		
Date	Signature		
	CEO Jan Knop		
	100000000000000000000000000000000000000		



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Meet all, of the requirements of the:

Issue:	Comments:		
Product name	KK101: Ping-Pong switch (with cable)		
Product description	Personal activator for a patient/client with special needs for calling		
	assistance. Activation by pushing a ping-pong ball.		
Serial numbers	Valid from S/N: 1XXXXX, S/N located on product.		
Basic UDI-DI	574400285KK9014E		
Classification according to MDR	Class I, Rule 1		
SRN: Single Registration Number	DK-MF-000025631		
Route of conformity for all	Annex I General safety and performance requirements.		
variants of the product	Annex II Technical documentation.		
	Annex III Technical documentation on post-market surveillance.		
Other relevant legislation, and	EN 301 498-1 V2.2.3		
applicable harmonized	EN 301 489-3 V3.1.1		
standards, and normative	EN 50130-4:2011 + 2014		
documents.	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		
N	ISO 14971:2019 KNOP ELEKTRONIK A/S		
Manufacturer:			
Telephone: Owner/ Position:	+45 97 84 04 44		
	CEO Jan Knop DK28305249		
Company No.:	Signature		
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Meet all, of the requirements of the:

Issue:	Comments:		
Product name	KK901P: Ping-Pong switch (with position detector)		
8	KK901: Ping-Pong switch (without position detector)		
Product description	Personal transmitter for a patient/client with special needs for calling		
•	assistance. Activation by pushing a ping-pong ball.		
Serial numbers	Valid from S/N: 1XXXXX, S/N located on product.		
Basic UDI-DI	574400285KK9014E		
Classification according to MDR	Class I, Rule 1		
SRN: Single Registration Number	DK-MF-000025631		
Route of conformity for all	Annex I General safety and performance requirements.		
variants of the product	Annex II Technical documentation.		
	Annex III Technical documentation on post-market surveillance.		
Other relevant legislation, and	EN 301 498-1 V2.2.3		
applicable harmonized	EN 301 489-3 V3.1.1		
standards, and normative	EN 50130-4:2011 + 2014		
documents.	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:	KNOP ELEKTRONIK A/S		
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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).

Issue:	Comments:		
Product name	LAK901: Sound to alarm		
	MI901: External microphone		
Product description	Transmitter for a patient/client with special needs. The		
~ .	transmission is activated when the patient/client makes a		
	noise/sound for calling assistance.		
Serial numbers	Valid from SN: 1XXXXX, S/N located on product.		
Basic UDI-DI	574400285LAK9012T		
Classification according to MDR	Class I, Rule 1		
SRN: Single Registration Number	DK-MF-000025631		
Route of conformity for all	Annex I General safety and performance requirements.		
variants of the product	Annex II Technical documentation.		
*	Annex III Technical documentation on post-market		
	surveillance.		
Other relevant legislation, and	EN 301 498-1 V2.2.3		
applicable harmonized	EN 301 489-3 V3.1.1		
standards, and normative	EN 50130-4:2011 + 2014		
documents.	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:	KNOP ELEKTRONIK A/S		
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Issue:	Comments);	
Product name	LS901 Light Slave		
Product description	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.		
Serial numbers	Valid from S/N: 1XXXXX, S/N located on product.		
Basic UDI-DI	574400285LS	S9016H	
Classification according to MDR	Class I, Rule		
SRN: Single Registration Number	DK-MF-00002	25631	
Route of conformity for all	Annex I	General safety and performance requirements.	
variants of the product	Annex II	Technical documentation.	
	Annex III	Technical documentation on post-market	
	surveillance.		
Other relevant legislation, and	EN 301 498-1 V2.2.3		
applicable harmonized	EN 301 489-3 V3.1.1		
standards, and normative	EN 50130-4:2011 + 2014		
documents.	EN 300 220-1 V3.1.1		
	EN 300 220-2 V3.1.1		
9	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		
		etive 1907/2006/EU	
	manager and the property and the second	ve 2011/65/EU	
BH	ISO 14971:2019 KNOP ELEKTRONIK A/S		
Manufacturer:			
Telephone: Owner/ Position:	+45 97 84 04 CEO Jan Kno		
CONTROL CONTRO	DK28305249	γ γ	
Company No.:	Signature		
Date	Signature		
	CEO Jan Kno		
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Issue:	Comments:		
Product name	MR902 Master F	Repeater	
Product description	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.		
Serial numbers	Valid from S/N: 1XXXXX, S/N located on product.		
Basic UDI-DI	574400285MR9026P		
Classification according to MDR	Class I, Rule 1		
SRN: Single Registration Number	DK-MF-000025631		
Route of conformity for all		safety and performance requirements.	
variants of the product		al documentation.	
		al documentation on post-market	
	surveillance.		
Other relevant legislation, and	EN 301 498-1 V2.2.3		
applicable harmonized	EN 301 489-3 V3.1.1		
standards, and normative	EN 50130-4:2011 + 2014		
documents.	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 2011/6	5/EU	
	ISO 14971:2019		
Manufacturer:	KNOP ELEKTRONIK	4/5	
Telephone:	+45 97 84 04 44		
Owner/ Position:	CEO Jan Knop		
Company No.:	DK28305249		
Date	Signature		
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Meet all, of the requirements of the:

Issue:	Comments:		
Product name	PIR900 Motion detect/Bed guard		
Product description	Personal transmitter for a patient/client with special needs for calling		
	assistance.		
Serial numbers	Valid from S/N: 1XXXXX, S/N located on product.		
Basic UDI-DI	574400285PIR9008N		
Classification according to MDR	Class I, Rule 1		
SRN: Single Registration Number	DK-MF-000025631		
Route of conformity for all	Annex I General safety and performance requirements.		
variants of the product	Annex II Technical documentation.		
	Annex III Technical documentation on post-market surveillance.		
Other relevant legislation, and	EN 301 498-1 V2.2.3		
applicable harmonized	EN 301 489-3 V3.1.1		
standards, and normative	EN 50130-4:2011 + 2014		
documents.	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:	KNOP ELEKTRONIK A/S		
Telephone:	+45 97 84 04 44		
Owner/ Position:	CEO Jan Knop		
Company No.:	DK28305249		
Date	Signature		
	CEO Jan Knop		



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Issue:	Comments	s:	
Product name	POS901:	With internal antenna	
	POS901L:	External loop antenna	
	POS901S:	External antenna for POS901	
Product description	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.		
Serial numbers		N: 1XXXXX, S/N located on product.	
Basic UDI-DI	574400285P		
Classification according to MDR	Class I, Rule		
SRN: Single Registration Number	DK-MF-0000	25631	
Route of conformity for all	Annex I	General safety and performance requirements.	
variants of the product	Annex II	Technical documentation.	
	Annex III	Technical documentation on post-market	
		surveillance.	
Other relevant legislation, and	EN 301 498-1 V2.2.3		
applicable harmonized	EN 301 489-3 V3.1.1		
standards, and normative	EN 50130-4:2011 + 2014		
documents.	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		
	ETSI EN 300 330 V2.1.1		
	REACH Directive 1907/2006/EU RoHS Directive 2011/65/EU		
	ISO 14971:20		
Manufacturer:		TRONIK A/S	
Telephone:	+45 97 84 04		
Owner/ Position:	CEO Jan Kno		
Company No.:	DK28305249		
Date	Signature	A	
	CEO Jan Kno	op Company	



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Issue:	Comments:		
Product name	RP901 Repeater		
Product description	RP901 extents the broadcast range of transmitters in a		
	standalone system.		
Serial numbers	Valid from S/N: 1XXXXX, S/N located on product.		
Basic UDI-DI	574400285RP9017W		
Classification according to MDR	Class I, Rule 1		
SRN: Single Registration Number	DK-MF-000025631		
Route of conformity for all	Annex I General safety and performance requirements.		
variants of the product	Annex II Technical documentation.		
	Annex III Technical documentation on post-market		
	surveillance.		
Other relevant legislation, and	EN 301 498-1 V2.2.3		
applicable harmonized	EN 301 489-3 V3.1.1		
standards, and normative	EN 50130-4:2011 + 2014		
documents.	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		
Manufacturer:	ISO 14971:2019 KNOP ELEKTRONIK A/S		
Telephone:	+45 97 84 04 44		
Owner/ Position:	CEO Jan Knop		
Company No.:	DK28305249		
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Issue:	Comments	:	
Product name	RP902 Repeater		
Product description	RP902 extents the broadcast range of transmitters either in		
•	system or standalone. Typically, a repeater system consists of		
	one MR902 (master) and several RP902.		
Serial numbers	Valid from S/N: 1XXXXX, S/N located on product.		
Basic UDI-DI	574400285RF	P9027Y	
Classification according to MDR	Class I, Rule	1	
SRN: Single Registration Number	DK-MF-00002	25631	
Route of conformity for all	Annex I	General safety and performance requirements.	
variants of the product	Annex II	Technical documentation.	
	Annex III	Technical documentation on post-market	
	surveillance.		
Other relevant legislation, and	EN 301 498-1 V2.2.3		
applicable harmonized	EN 301 489-3 V3.1.1		
standards, and normative	EN 50130-4:2011 + 2014		
documents.	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		
		ve 2011/65/EU	
	ISO 14971:2019		
Manufacturer:	KNOP ELEKT		
Telephone:	+45 97 84 04		
Owner/ Position:	CEO Jan Kno	q	
Company No.:	DK28305249	1	
Date	Signature		
	0001	- file	
	CEO Jan Kno	р	



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Meet all, of the requirements of the:

oduct name	PU101: Blow switch (with cable)		
oduct description	Personal switch for a patient/client with special needs for calling		
	assistance. Activation by blowing into the product.		
erial numbers	Valid from S/N: 1XXXXX, S/N located on product.		
asic UDI-DI	574400285PU9018B		
assification according to MDR	Class I, Rule 1		
RN: Single Registration Number			
oute of conformity for all	Annex I General safety and performance requirements.		
riants of the product	Annex II Technical documentation.		
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	EN 62368-1:2020		
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	REACH Directive 1907/2006/EU		
	RoHS Directive 2011/65/EU		
anufacturer:	ISO 14971:2019 KNOP ELEKTRONIK A/S		
anutacturer: elephone:	+45 97 84 04 44		
wner/ Position:	CEO Jan Knop		
ompany No.:	DK28305249		
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Issue:	Comments:
Product name	PU901P: Blow switch (with position detector)
	PU901: Blow switch (without position detector)
Product description	Personal transmitter for a patient/client with special needs for calling
	assistance. Activation by blowing into the product.
Serial numbers	Valid from S/N: 1XXXXX, S/N located on product.
Basic UDI-DI	574400285PU9018B
Classification according to MDR	Class I, Rule 1
SRN: Single Registration Number	DK-MF-000025631
Route of conformity for all	Annex I General safety and performance requirements.
variants of the product	Annex II Technical documentation.
	Annex III Technical documentation on post-market surveillance.
Other relevant legislation, and	EN 301 498-1 V2.2.3
applicable harmonized	EN 301 489-3 V3.1.1
standards, and normative	EN 50130-4:2011 + 2014
documents.	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:	KNOP ELEKTRONIK A/S
Telephone:	+45 97 84 04 44
Owner/ Position:	CEO Jan Knop
Company No.:	DK28305249
Date	Signature
	19///
	CEO lan Knop
	CEO Jan Knop



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:

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).

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	Annex I: General safety and performance requirements.
variants of the product	Annex II: Technical documentation.
	Annex III: Technical documentation on post-market
	surveillance.
Other relevant legislation, and	EN 301 498-1 V2.2.3
applicable harmonized	EN 301 489-3 V3.1.1
standards, and normative	EN 50130-4:2011 + 2014
documents.	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
N.H	ISO 14971:2019
Manufacturer:	KNOP ELEKTRONIK A/S
Telephone:	+45 97 84 04 44
Owner/Position:	CEO Jan Knop
Company No.:	DK28305249
Date	Signature
	16 V
	CEO Jan Knop
	OEO Jan Mioh



To whom it may concern

Struer, Denmark, Juni, 2022

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Meet all, of the requirements of the:

Issue:	Comments:
Product name	RX901B: Receiver with LCD
	RX901B-4: 4-ch Receiver with LCD
Product description	Programmable receiver. The product will receive the assistance
-	request from the transmitters programmed into the receiver.
Serial numbers	Valid from S/N: 1XXXXX, S/N located on product.
Basic UDI-DI	574400285RX901B95
Classification according to MDR	Class I, Rule 1
SRN: Single Registration Number	DK-MF-000025631
Route of conformity for all	Annex I General safety and performance requirements.
variants of the product	Annex II Technical documentation.
	Annex III Technical documentation on post-market surveillance.
Other relevant legislation, and	EN 301 498-1 V2.2.3
applicable harmonized	EN 301 489-3 V3.1.1
standards, and normative	EN 50130-4:2011 + 2014
documents.	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:	KNOP ELEKTRONIK A/S
Telephone:	+45 97 84 04 44
Owner/ Position:	CEO Jan Knop
Company No.:	28305249
Date	Signature
	CEO lan Man
	CEO Jan Knop



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Issue:	Comments:
Product name	RX901C Receiver with 4 relay outputs.
Product description	The receiver can be programmed to receive 4 different
	transmitters and activate a relay output according.
Serial numbers	Valid from SN: 1XXXXX, S/N located on product
Basic UDI-DI	574400285RX901C97
Classification according to MDR	Class I, Rule 1
SRN: Single Registration Number	DK-MF-000025631
Route of conformity for all	Annex I General safety and performance requirements.
variants of the product	Annex II Technical documentation.
	Annex III Technical documentation on post-market
	surveillance.
Other relevant legislation, and	EN 301 498-1 V2.2.3
applicable harmonized	EN 301 489-3 V3.1.1
standards, and normative	EN 50130-4:2011 + 2014
documents.	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
BH f f f	ISO 14971:2019 KNOP ELEKTRONIK A/S
Manufacturer:	+45 97 84 04 44
Telephone: Owner/ Position:	
	CEO Jan Knop DK28305249
Company No.:	Signature
Date	Signature
,	CEO Jan Knop
	010 0011 1110



To whom it may concern

Struer, Denmark, Juni, 2022

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Issue:	Comments:
Product name	TR303417HF & TR303410HF: Transmitter with position detector.
Product description	Personal transmitter for a patient/client with special needs for calling
	assistance. Activation is via pressure mat TR303417HF or
	TR303410HF.
Serial numbers	Valid from S/N: 1XXXXX, S/N located on product.
Basic UDI-DI	574400285TR90192
Classification according to MDR	Class I, Rule 1
SRN: Single Registration Number	DK-MF-000025631
Route of conformity for all	Annex I General safety and performance requirements.
variants of the product	Annex II Technical documentation.
	Annex III Technical documentation on post-market surveillance.
Other relevant legislation, and	EN 301 498-1 V2.2.3
applicable harmonized	EN 301 489-3 V3.1.1
standards, and normative	EN 50130-4:2011 + 2014
documents.	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
Manufacturer:	ISO 14971:2019 KNOP ELEKTRONIK A/S
Telephone: Owner/ Position:	+45 97 84 04 44 CEO Jan Knop
Company No.:	DK28305249
Date	Signature
Date	Signature
	CEO Jan Knop



To whom it may concern

Struer, Denmark, Juni, 2022

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Meet all, of the requirements of the:

Issue:	Comments:
Product name	TX901 Alarm transmitter/Door Guard
Product description	Personal transmitter for a patient/client with special needs for calling
	assistance. Different activation methods apply.
Serial numbers	Valid from S/N: 1XXXXX, S/N located on product.
Basic UDI-DI	574400285TX901AC
Classification according to MDR	Class I, Rule 1
SRN: Single Registration Number	DK-MF-000025631
Route of conformity for all	Annex I General safety and performance requirements.
variants of the product	Annex II Technical documentation.
	Annex III Technical documentation on post-market surveillance.
Other relevant legislation, and	EN 301 498-1 V2.2.3
applicable harmonized	EN 301 489-3 V3.1.1
standards, and normative	EN 50130-4:2011 + 2014
documents.	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:	KNOP ELEKTRONIK A/S
	+45 97 84 04 44
Telephone: Owner/ Position:	CEO Jan Knop
Company No.:	DK28305249
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Date	Oignature
	CEO Jan Knop



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Meet all, of the requirements of the:

Issue:	ves 90/385/EEC and 93/42/EEC, with amendments (MDR). Comments:
Product name	TX901A: Bracelet transmitter (without position detector)
	TX901A-T: Necklace transmitter large push button
	TX901A-H: Necklace transmitter
	TX901AP: Bracelet transmitter (with position detector)
Product description	Personal transmitter for a patient/client with special needs for calling
-	assistance. Activation methods according to the product.
Serial numbers	Valid from S/N: 1XXXXX, S/N located on product.
Basic UDI-DI	574400285TX901A9V
Classification according to MDR	Class I, Rule 1
SRN: Single Registration Number	DK-MF-000025631
Route of conformity for all	Annex I General safety and performance requirements.
variants of the product	Annex II Technical documentation.
	Annex III Technical documentation on post-market surveillance.
Other relevant legislation, and	EN 301 498-1 V2.2.3
applicable harmonized	EN 301 489-3 V3.1.1
standards, and normative	EN 50130-4:2011 + 2014
documents.	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
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	REACH Directive 1907/2006/EU
	RoHS Directive 2011/65/EU
	ISO 14971:2019
Manufacturer:	KNOP ELEKTRONIK A/S
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Owner/ Position:	CEO Jan Knop
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4	CEO Jan Knop
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Issue:	Comments:
Product name	TX901D 1-channel transmitter
Product description	Transmitter for a patient/client with special needs. The
	transmission is activated from an external input to call for
	assistance.
Serial numbers	Valid from SN: 1xxxxx, S/N located on product.
Basic UDI-DI	574400285TX901DA3
Classification according to MDR	Class I, Rule 1
SRN: Single Registration Number	DK-MF-000025631
Route of conformity for all	Annex I General safety and performance requirements.
variants of the product	Annex II Technical documentation.
e	Annex III Technical documentation on post-market
	surveillance.
Other relevant legislation, and	EN 301 498-1 V2.2.3
applicable harmonized	EN 301 489-3 V3.1.1
standards, and normative	EN 50130-4:2011 + 2014
documents.	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:	KNOP ELEKTRONIK A/S
Telephone:	+45 97 84 04 44
Owner/ Position:	CEO Jan Knop
Company No.:	DK28305249
Date	Signature
	J. J
	CEO Jan Knop