



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:

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	CT901 Controller
Product description	The CT901 is a controller for Knop products.
Serial numbers	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 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.:	KNOP ELEKTRONIK A/S +45 97 84 04 44 CEO Jan Knop DK28305249
Date: 01/10/2024	Signature:  CEO Jan Knop

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:

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	CT901BED Bed monitor
Product description	The CT901BED is a specialized controller for client/bed/light.
Serial numbers	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 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.:	KNOP ELEKTRONIK A/S +45 97 84 04 44 CEO Jan Knop DK28305249
Date 01/10/2024	Signature:  CEO Jan Knop



EC Declaration of Conformity Certificate

To whom it may concern

Struer, Denmark, February 2026

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	EPI901 Seizure alarm
Product description	Radio transmitter for a patient/client with special needs.
Serial numbers	S/N located on product.
Basic UDI-DI	574400285EPI9014P
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.	Regulation 2017/745/EU MDR Regulation 1907/2006/EU REACH Directive 2011/65/EU RoHS Directive 2012/19/EU WEEE Directive 2014/35/EU Low Voltage Directive EN 14971:2019 Risk Management for Medical Devices EN 301 498-1 V2.2.3 Electromagnetic Compatibility EN 301 489-3 V3.1.1 Electromagnetic Compatibility EN 50130-4:2011 + 2014 Immunity alarm systems EN 300 220-1 V3.1.1 Short Range Devices EN 300 220-2 V3.1.1 Short Range Devices EN 300 220-3 V2.1.1 Short Range Devices EN 60601-1-2:2014 + 1-11:2015 Electromagnetic compatibility (Medical) EN 62133-2:2017 + A1:2021 Battery safety requirements EN 62368-1:2020 Electrical safety EN 63000:2018 Hazardous substances
Manufacturer: Telephone: Owner/ Position: Company No.:	KNOP ELEKTRONIK A/S +45 97 84 04 44 CEO Jan Knop DK28305249
Date	Signature:  CEO Jan Knop
05/02/2026	

Version 1.0 (TST) 05/02/2026

© **KNOP Elektronik A/S**

Fabriksvej 20 ● DK-7600 Struer ● knop@knop.dk ● knop.dk ● +45 97840444

EC Declaration of Conformity Certificate

To whom it may concern

Struer, Denmark, February 2026

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	EPI901S Sensor
Product description	Extern sensor for EPI901
Serial numbers	S/N located on product.
Basic UDI-DI	574400285EPI9014P
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.	Regulation 2017/745/EU MDR Regulation 1907/2006/EU REACH Directive 2011/65/EU RoHS Directive 2012/19/EU WEEE Directive 2014/35/EU Low Voltage Directive EN 14971:2019 Risk Management for Medical Devices EN 301 498-1 V2.2.3 Electromagnetic Compatibility EN 301 489-3 V3.1.1 Electromagnetic Compatibility EN 50130-4:2011 + 2014 Immunity alarm systems EN 300 220-1 V3.1.1 Short Range Devices EN 300 220-2 V3.1.1 Short Range Devices EN 300 220-3 V2.1.1 Short Range Devices EN 60601-1-2:2014 + 1-11:2015 Electromagnetic compatibility (Medical) EN 62133-2:2017 + A1:2021 Battery safety requirements EN 62368-1:2020 Electrical safety EN 63000:2018 Hazardous substances
Manufacturer: Telephone: Owner/ Position: Company No.:	KNOP ELEKTRONIK A/S +45 97 84 04 44 CEO Jan Knop DK28305249
Date	Signature:  CEO Jan Knop
05/02/2026	

Version 1.0 (TST) 05/02/2026

© **KNOP Elektronik A/S**

Fabriksvej 20 ● DK-7600 Struer ● knop@knop.dk ● knop.dk ● +45 97840444



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:

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	KK100: 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	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 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.:	KNOP ELEKTRONIK A/S +45 97 84 04 44 CEO Jan Knop DK28305249
Date 01/10/2024	Signature:  CEO Jan Knop

© **KNOP Elektronik A/S**

Fabriksvej 20 ● DK-7600 Struer ● knop@knop.dk ● knop.dk ● +45 97840444



EC Declaration of Conformity Certificate

To whom it may concern

Struer, Denmark, February 2026

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	KK901P Ping-Pong switch
Product description	Transmitter for a patient/client with special needs for calling assistance.
Serial numbers	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 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.	Regulation 2017/745/EU MDR Regulation 1907/2006/EU REACH Directive 2011/65/EU RoHS Directive 2012/19/EU WEEE Directive 2014/35/EU Low Voltage Directive EN 14971:2019 Risk Management for Medical Devices EN 301 498-1 V2.2.3 Electromagnetic Compatibility EN 301 489-3 V3.1.1 Electromagnetic Compatibility EN 50130-4:2011 + 2014 Immunity alarm systems EN 300 220-1 V3.1.1 Short Range Devices EN 300 220-2 V3.1.1 Short Range Devices EN 300 220-3 V2.1.1 Short Range Devices EN 60601-1-2:2014 + 1-11:2015 Electromagnetic compatibility (Medical) EN 62133-2:2017 + A1:2021 Battery safety requirements EN 62368-1:2020 Electrical safety EN 63000:2018 Hazardous substances
Manufacturer: Telephone: Owner/ Position: Company No.:	KNOP ELEKTRONIK A/S +45 97 84 04 44 CEO Jan Knop DK28305249
Date	Signature:  CEO Jan Knop
05/02/2026	

Version 1.1 (TST) 05/02/2026

© **KNOP Elektronik A/S**

Fabriksvej 20 ● DK-7600 Struer ● knop@knop.dk ● knop.dk ● +45 97840444



EC Declaration of Conformity Certificate

To whom it may concern

Struer, Denmark, February 2026

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	LAK901 Sound to alarm MI901 External microphone
Product description	Radio transmitter for a patient/client with special needs.
Serial numbers	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 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.	Regulation 2017/745/EU MDR Regulation 1907/2006/EU REACH Directive 2011/65/EU RoHS Directive 2012/19/EU WEEE Directive 2014/35/EU Low Voltage Directive EN 14971:2019 Risk Management for Medical Devices EN 301 498-1 V2.2.3 Electromagnetic Compatibility EN 301 489-3 V3.1.1 Electromagnetic Compatibility EN 50130-4:2011 + 2014 Immunity alarm systems EN 300 220-1 V3.1.1 Short Range Devices EN 300 220-2 V3.1.1 Short Range Devices EN 300 220-3 V2.1.1 Short Range Devices EN 60601-1-2:2014 + 1-11:2015 Electromagnetic compatibility (Medical) EN 62133-2:2017 + A1:2021 Battery safety requirements EN 62368-1:2020 Electrical safety EN 63000:2018 Hazardous substances
Manufacturer: Telephone: Owner/ Position: Company No.:	KNOP ELEKTRONIK A/S +45 97 84 04 44 CEO Jan Knop DK28305249
Date 05/02/2026	Signature:  CEO Jan Knop

Version 1.2 (TST) 05/02/2026

© **KNOP Elektronik A/S**

Fabriksvej 20 ● DK-7600 Struer ● knop@knop.dk ● knop.dk ● +45 97840444



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:

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	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	S/N located on product.
Basic UDI-DI	574400285LS9016H
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.:	KNOP ELEKTRONIK A/S +45 97 84 04 44 CEO Jan Knop DK28305249
Date: 01/10/2024	Signature:  CEO Jan Knop



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:

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	MR902 Master 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	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 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.:	KNOP ELEKTRONIK A/S +45 97 84 04 44 CEO Jan Knop DK28305249
Date 01/10/2024	Signature:  CEO Jan Knop



EC Declaration of Conformity Certificate

To whom it may concern

Struer, Denmark, February 2026

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	PIR901 Motion detector
Product description	Radio transmitter for a patient/client with special needs.
Serial numbers	S/N located on product.
Basic UDI-DI	574400285PIR9018Q
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.	Regulation 2017/745/EU MDR Regulation 1907/2006/EU REACH Directive 2011/65/EU RoHS Directive 2012/19/EU WEEE Directive 2014/35/EU Low Voltage Directive EN 14971:2019 Risk Management for Medical Devices EN 301 498-1 V2.2.3 Electromagnetic Compatibility EN 301 489-3 V3.1.1 Electromagnetic Compatibility EN 50130-4:2011 + 2014 Immunity alarm systems EN 300 220-1 V3.1.1 Short Range Devices EN 300 220-2 V3.1.1 Short Range Devices EN 300 220-3 V2.1.1 Short Range Devices EN 60601-1-2:2014 + 1-11:2015 Electromagnetic compatibility (Medical) EN 62133-2:2017 + A1:2021 Battery safety requirements EN 62368-1:2020 Electrical safety EN 63000:2018 Hazardous substances
Manufacturer: Telephone: Owner/ Position: Company No.:	KNOP ELEKTRONIK A/S +45 97 84 04 44 CEO Jan Knop DK28305249
Date 05/02/2026	Signature:  CEO Jan Knop

Version 1.0 (TST) 05/02/2026

© **KNOP Elektronik A/S**

Fabriksvej 20 ● DK-7600 Struer ● knop@knop.dk ● knop.dk ● +45 97840444

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:

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	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	S/N located on product.
Basic UDI-DI	574400285POS901AZ
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 301 498-3 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
Manufacturer: Telephone: Owner/ Position: Company No.:	KNOP ELEKTRONIK A/S +45 97 84 04 44 CEO Jan Knop DK28305249
Date <i>01/10/2024</i>	Signature:  CEO Jan Knop

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:

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	PU101: Blow switch (with cable)
Product description	Personal switch for a patient/client with special needs for calling assistance. Activation by blowing into the product.
Serial numbers	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 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.:	KNOP ELEKTRONIK A/S +45 97 84 04 44 CEO Jan Knop DK28305249
Date 01/10/2024	Signature:  CEO Jan Knop



EC Declaration of Conformity Certificate

To whom it may concern

Struer, Denmark, February 2026

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	PU901P Blow switch
Product description	Personal transmitter for a patient/client with special needs.
Serial numbers	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 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.	Regulation 2017/745/EU MDR Regulation 1907/2006/EU REACH Directive 2011/65/EU RoHS Directive 2012/19/EU WEEE Directive 2014/35/EU Low Voltage Directive EN 14971:2019 Risk Management for Medical Devices EN 301 498-1 V2.2.3 Electromagnetic Compatibility EN 301 489-3 V3.1.1 Electromagnetic Compatibility EN 50130-4:2011 + 2014 Immunity alarm systems EN 300 220-1 V3.1.1 Short Range Devices EN 300 220-2 V3.1.1 Short Range Devices EN 300 220-3 V2.1.1 Short Range Devices EN 60601-1-2:2014 + 1-11:2015 Electromagnetic compatibility (Medical) EN 62133-2:2017 + A1:2021 Battery safety requirements EN 62368-1:2020 Electrical safety EN 63000:2018 Hazardous substances
Manufacturer: Telephone: Owner/ Position: Company No.:	KNOP ELEKTRONIK A/S +45 97 84 04 44 CEO Jan Knop DK28305249
Date: 05/02/2016	Signature:  CEO Jan Knop

Version 1.1 (TST) 05/02/2026

© **KNOP** Elektronik A/S

Fabriksvej 20 ● DK-7600 Struer ● knop@knop.dk ● knop.dk ● +45 97840444



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:

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	RP902 Repeater
Product description	RP902 extends the broadcast range of transmitters either in system or standalone. Typically, a repeater system consists of one MR902 (master) and several RP902.
Serial numbers	S/N located on product.
Basic UDI-DI	574400285RP9027Y
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.:	KNOP ELEKTRONIK A/S +45 97 84 04 44 CEO Jan Knop DK28305249
Date: 01/10/2024	Signature:  CEO Jan Knop



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:

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	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.:	KNOP ELEKTRONIK A/S +45 97 84 04 44 CEO Jan Knop DK28305249
Date: <i>01/10/2024</i>	Signature:  CEO Jan Knop



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:

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	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	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 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.:	KNOP ELEKTRONIK A/S +45 97 84 04 44 CEO Jan Knop 28305249
Date: 01/10/2024	Signature:  CEO Jan Knop



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:

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	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	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 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.:	KNOP ELEKTRONIK A/S +45 97 84 04 44 CEO Jan Knop DK28305249
Date: 01/10/2024	Signature:  CEO Jan Knop



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:

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	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	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 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.:	KNOP ELEKTRONIK A/S +45 97 84 04 44 CEO Jan Knop DK28305249
Date: 01/10/2024	Signature:  CEO Jan Knop



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:

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	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	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 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.:	KNOP ELEKTRONIK A/S +45 97 84 04 44 CEO Jan Knop DK28305249
Date: <i>01/10/2024</i>	Signature:  CEO Jan Knop



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:

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	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	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 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.:	KNOP ELEKTRONIK A/S +45 97 84 04 44 CEO Jan Knop DK28305249
Date 01/10/2024	Signature:  CEO Jan Knop



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:

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	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	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 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.:	KNOP ELEKTRONIK A/S +45 97 84 04 44 CEO Jan Knop DK28305249
Date 01/10/2024	Signature:  CEO Jan Knop



EC Declaration of Conformity Certificate

To whom it may concern

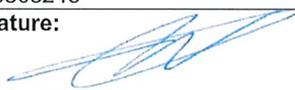
Struer, Denmark, February 2026

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	PIR100 Motion detector (relay version)
Product description	Motion detector for a patient/client with special needs.
Serial numbers	S/N located on product.
Basic UDI-DI	574400285PIR9018Q
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.	Regulation 2017/745/EU MDR Regulation 1907/2006/EU REACH Directive 2011/65/EU RoHS Directive 2012/19/EU WEEE Directive 2014/35/EU Low Voltage Directive EN 14971:2019 Risk Management for Medical Devices EN 301 498-1 V2.2.3 Electromagnetic Compatibility EN 301 489-3 V3.1.1 Electromagnetic Compatibility EN 50130-4:2011 + 2014 Immunity alarm systems EN 60601-1-2:2014 + 1-11:2015 Electromagnetic compatibility (Medical) EN 62133-2:2017 + A1:2021 Battery safety requirements EN 62368-1:2020 Electrical safety EN 63000:2018 Hazardous substances
Manufacturer: Telephone: Owner/ Position: Company No.:	KNOP ELEKTRONIK A/S +45 97 84 04 44 CEO Jan Knop DK28305249
Date 05/02/2026	Signature:  CEO Jan Knop

1

Version 1.0 (TST) 05/02/2026

© **KNOP Elektronik A/S**

Fabriksvej 20 ● DK-7600 Struer ● knop@knop.dk ● knop.dk ● +45 97840444