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Manufacturer	**Redsense Medical AB (publ)**	
Single Registration Number SRN (EU MDR, Article 31)	SE-MF-000005240	
Address of registered place of business	Storgatan 36 302 43 Halmstad	
Declaration of Conformity	Annex IV of the European Medical Devices Regulation 2017/745 UK Medical Devices Regulations 2002 No. 618 Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU on the restriction of the use of certain hazardous substances with the harmonized norm EN IEC 63000:2018, including the delegated Directive EU 2015/863 (RoHS 3) the modification of Annex II to Directive 2011/65 / EU 2014/53/EU – Radio Equipment Directive (RED) Part 15 of the FCC Rules Industry Canada's license-exempt RSSs UK Radio Equipment Regulations 2017	
Product	**Redsense Clamp System**	
Product identification	Product identification (article number)	Basic UDI-DI (Annex VI, Part C)
Redsense Clamp System	RB-1-RB201	7350078030373X2
Redsense Bloodline Clamp	RB-1-RB201-C	7350078030380WX
Redsense Dongle	RB-1-RB201-D	7350078030397XG
Bloodline Clamp connector cable USB-USB	RK-1-RK201-B	7350078030366X5

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Intended purpose	The Redsense Clamp System is a bloodline clamp device used as an accessory to the Redsense Alarm System to prevent severe blood loss from venous needle dislodgement or venous catheter-bloodline disconnection during hemodialysis. During treatment, the Bloodline Clamp is attached to the venous bloodline close to the dialysis machine with the indicators visible to the operator. When the Redsense Alarm System detects blood leakage at the venous access site and starts to alarm, a wireless signal is sent to the Redsense Bloodline Clamp via the Redsense Dongle. The Redsense Clamp then clamps the bloodline to prevent severe blood loss. All use must be administrated under physician's prescription and must be observed by a trained and qualified person considered to be competent in the use of this device by the prescribing physician.
Classification and rule EU MDR 2017/745	According to rule 1 and rule 13 in Annex VIII MDR (EU) 2017/745 shall the Redsense Clamp System be classified as medical devices class I
Classification and rule UK MDR 2002 No. 618	According to rule 1 and rule 12 in Appendix IX in MDD 93/42/EEC, and thus also according to UK MDR 2002 No. 618, the Redsense Clamp System shall be classified as a medical devices class I.
Classification and rule CAN SOR-98-282	According to rule 7 subrule (1) and rule 12 in Schedule 1 Part 1 in SOR-98-282 the Redsense Clamp System shall be classified as a medical device class I.
Classification EU Directive 2014/53/EU RED	Redsense Clamp System is classified as a radio equipment Class 1, as it can be placed on the market without restrictions. Subclass 22, Wideband Data Transmission Systems 2400 – 2483,5 MHz
Classification UK Radio Equipment Regulation 2017	Redsense Clamp System is classified as a radio equipment Class 1, as it can be placed on the market without restrictions.
Common Specification(s) used to which conformity is declared	N/A

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Notified body and identification number	N/A
Conformity assessment procedure performed	Article 52 paragraph 7 of the European Medical Devices Regulation 2017/745
Certificate No	TVC 2106794-001s 2106794STO-001 IEC 60601-1 (signed) 2106794STO-002 IEC 60601-1-8 (signed) 2106794STO-003 IEC 60601-1-11 (signed) 2106794STO-004 IEC 60601-1-6 (signed) 2106794STO-005 IEC 62304 (signed) 2106794STO-101 2106794STO-102 DE24N5WT 001 EN 300 328_BloodLine Clamp_extsigned DE24NCFW 001 EN 62479_BloodLine Clamp_extsigned DE24C6EM 001_FCC MPE Evalualtion_extsigned DE240SKM 001_FCC 15.247_extsigned DE249P1Q 001 EN 300 328_Dongle_extsigned DE24S31G 001 EN 62479_Dongle_extsigned DE24IZNB 001_FCC MPE Evalualtion_extsigned DE24T4B3 001_FCC 15.247_extsigned-1 105820975LEX-002 ANSI C63.27 Wireless Coexistence Final
Additional information, if applicable	N/A

The following standards were used to assess the device	
European Medical Devices Regulation 2017/745	IEC 60601-1:2005+A1+A2 IEC 60601-1-2:2014 + A1:2020 IEC 60601-1-8:2006+A1+A2 IEC 60601-1-6:2010+A1+A2 IEC 60601-1-11:2015+A1 ISO 14971:2019 IEC 62366-1:2015+A1 IEC 62304:2006+A1 ETSI EN 301 489-1 V2.2.3 ETSI EN 301 489-17 V3.2.4

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The following standards were used to assess the device	
2014/53/EU – Radio Equipment Directive (RED)	ETSI EN 300 328 V2.2.2 ETSI EN 301 489-1 V2.2.3 ETSI EN 301 489-17 V3.2.4 EN 62479:2010 EN 50663:2017
Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU on the restriction of the use of certain hazardous substances, including the delegated Directive EU 2015/863 (RoHS 3) the modification of Annex II to Directive 2011/65 / EU	All included components and parts have certifications to ensure RoHS compliance
Part 15 of the FCC Rules	FCC CFR 47 Part 15 Subpart C - §15.247 ANSI C63.10:2013 KDB 558074 D01 DTS Measurement Guidance v05 KDB 996369 D04 Module Integration Guide v01 ANSI C63.27:2021 AAMI TIR69:2020
Medical Devices Regulations (SOR/98-282)	IEC 60601-1:2005+A1+A2 AAMI/IEC 60601-1:2005+A1:2012+A2:2021 CAN/CSA-C22.2 No. 60601-1:14+A2:22 IEC 60601-1-2:2014 + A1:2020 IEC 60601-1-8:2006+A1+A2 IEC 60601-1-6:2010+A1+A2 IEC 60601-1-11:2015+A1 ISO 14971:2019 IEC 62366-1:2015+A1 IEC 62304:2006+A1
Industry Canada's license-exempt RSSs	ISED RSS-247 Issue 3 2023 ANSI C63.10:2013 KDB 558074 D01 DTS Measurement Guidance v05 KDB 996369 D04 Module Integration Guide v01

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The following standards were used to assess the device	
UK Medical Devices Regulations 2002 No. 618	IEC 60601-1:2005+A1+A2 AAMI/IEC 60601-1:2005+A1:2012 CAN/CSA-C22.2 No. 60601-1:14+A2:22 IEC 60601-1-2:2014 + A1:2020 IEC 60601-1-8:2006+A1+A2 IEC 60601-1-6:2010+A1+A2 IEC 60601-1-11:2015+A1 ISO 14971:2019 IEC 62366-1:2015+A1 IEC 62304:2006+A1 ETSI EN 301 489-1 V2.2.3 ETSI EN 301 489-17 V3.2.4
UK Radio Equipment Regulations 2017	ETSI EN 300 328 V2.2.2 ETSI EN 301 489-1 V2.2.3 ETSI EN 301 489-17 V3.2.4 EN 62479:2010 EN 50663:2017

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We, the manufacturer, hereby declare that the above-mentioned product(s) comply with

- European Medical Devices Regulation 2017/745
- UK Medical Devices Regulations 2002 No. 618
- Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU on the restriction of the use of certain hazardous substances with the harmonized norm EN IEC 63000:2018, including the delegated Directive EU 2015/863 (RoHS 3) the modification of Annex II to Directive 2011/65 / EU
- 2014/53/EU – Radio Equipment Directive (RED)
- UK Radio Equipment Regulations 2017
- Part 15 of the FCC Rules
- Industry Canada's license-exempt RSSs

into which we place the devices.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Signed in Halmstad, Sweden (Date)	2025-05-21
Name and authority (CEO)	Sebastien Bollue, CEO
Signature