REDSENSE

Titel/title	
DECLARATION OF CONFORMITY	See SOP-007

Manufacturer	Redsense Medical AB (publ)	
Single Registration Number SRN (MDR, Article 31)	Not available until Eudamed is in operation	
Address of registered place of business	Gyllenhammars väg 26 302 92 Halmstad	
Declaration of Conformity	Annex IV of the European Medical Devices Regulation 2017/745	
Product	Redsense	
Product identification	Product identification (article number)	Basic UDI-DI (Annex VI, Part C)
Redsense Alarm unit	RA-1-RA201	7350078030014
Redsense Alarm unit with PAS function	RP-1-RP201	7350078030250
Redsense Alarm Unit with Nurse Call function	RN-1-RN201	7350078030175
Fiber optic extension	RE-1-RE201	7350078030090
Redsense Venous Sensor Patch (100 pcs/box)	RS-100-RS201-S	7350078030083
Redsense Catheter Sensor Patch (50 pcs/box)	RL-50-RL201-S	7350078030229
Intended purpose	The Redsense Alarm System includes an alarm unit (AU) and one of two different single-use sensors and is used for monitoring patients undergoing hemodialysis at home or in clinical settings. The venous sensor is an adhesive dressing that is attached to the patient's skin over the puncture hole of the venous needle. Via a built-in fiber optical probe, it intends to monitor potential blood leakage caused by a disconnection or others. The catheter sensor wraps around the central venous catheter and is used for monitoring the connectors of the catheter. Via a built-in fiber optical probe, it intends to monitor potential blood leakage caused by a disconnection or others. The sensors are connected to the alarm unit via a fiber optic extension cable and in the event of bleeding the system will	

	sound an alarm. The alarm unit and the extension cable are intended to be reused. The alarm units with nurse call or PAS function are also intended to be connected by cable to external nurse call system or dialysis machine. 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	According to rule 1 and rule 11 in Annex VIII MDR (EU) 2017/745 shall the Redsense Alarm System, with the devices Alarm Unit, VND sensor and CVC sensor, shall all be classified as medical devices class I
Common Specification(s) used to which conformity is declared	N/A
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	6.6.1-2019-7540
Additional information, if applicable	N/A

We, the manufacturer, hereby declare that the above-mentioned product(s) comply with the European Medical Devices Regulation 2017/745 into which we place the devices.
This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Signed in Halmstad, Sweden (Date)	
Name and authority (CEO)	Patrik Byhmer, CEO
Signature	

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