

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 724688 R000

Manufacturer: CardiacSense Ltd.

Address:

6 Leshem St.
Northern Industrial Park
Caesarea
3079868
Israel

Single Registration Number: 514370204

EU Authorised Representative: MedNet EC-REP GmbH

Address:

Borkstrasse 10
48163 Münster
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-02-04**

Date: **2021-02-04**

Expiry Date: **2026-02-03**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

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Device Schedule: Class IIa

Device(s)	Risk Classification
Wearable medical devices for clinical parameters using electrocardiographic and photoplethysmographic measurements	Class IIa



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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference number	Action
Current	3149214	Initial Issue



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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 724688 R000

Date: 2021-02-04

Critical Subcontractor/Crucial Supplier	Service(s) supplied
A.Y. Electronics Ltd. Beit IsreLevi 58 Amal St, Kiryat Aire, POB 3272 Petach Tikva 4951358, Israel	Manufacture
P.M. Partner Manufacturing Ltd. 10 HaRotem St. Bar-Lev Industrial Park 7757210 Israel	Manufacture

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