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30 April 2021

Subject: **Letter of Authenticity of EC certificates**

To Whom It May Concern

BSI is designated as a Notified Body (Notified Body Number 2797) under the European Regulation(EU) 2017/745 . BSI has conducted a conformity assessment against the Regulation(EU) 2017/745 Annex IX Chapter I and III of the following medical device manufacturer:

CardiacSense Ltd.
6 Leshem St.,
Northern Industrial Park
Caesarea
3079868
Israel

BSI issued the EC Certificate ref. **MDR 724688 R000** to **CardiacSense Ltd.** with the following scope: See the **Device Schedule** bellow:

EC Certificate MDR 724688 R000:	Class
Wearable medical devices for clinical parameters using electrocardiographic and photoplethysmographic measurements	IIa

Under the Regulation(EU), a medical device manufacturer may prepare and complete a declaration of conformity for devices that fully meet the requirements of the Regulation(EU) and are within the scope of the Annex IX Chapter I and III. The medical device manufacturer listed above has provided a copy of a declaration of conformity for the devices listed herein.

BSI accepts that the device identified in the table is within the scope of BSI above certificate and therefore by following the declaration of conformity process and the requirements of the EU Member States, the medical device manufacturer is free to place these devices on the EU Market.

EC Certificate MDR 724688 R000:	Class
CardiacSense1	IIa
CS System 3 **	IIa

***: Comprising of CS Watch 3, CS3 Mobile app, CS3 Cloud app as system components.*

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Please contact the undersigned if you have any questions regarding this letter or the BSI certificate.

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