

EC DECLARATION OF CONFORMITY

Manufacturer: Saving, d.o.o.
Finžgarjeva ulica 4
SI-1000 Ljubljana, Slovenija

PRODUCT: Personal CARDiac activity monitoring system - PCARD

MODEL: Savvy

UMDNS: 36367

CLASSIFICATION: IIa according to Rule 10 of MDD, (Annex IX)

Hereby we declare that the above mentioned product complies with the essential requirements of medical device directive 93/42/EEC. All supporting documents are retained in the premises of the manufacturer.

The product was a subject of conformity assessment procedure in Annex II (Full quality assurance system), excluding section 4.

The company has implemented quality management system according to the requirements of standard: EN ISO 13485:2003/AC:2007.

Main Directives:

COUNCIL DIRECTIVE 93/42/EEC; As follows, the stated product is declared as **medical devices**;
RoHS Directive 2011/65/EU;
Directive 2014/53/EU;

Standards applied:

EN 60601-1:2006; EN 60601-1-2:2014; EN 60601-1-6:2010; EN ISO 62366:2010; EN ISO 62304:2006; EN ISO 14971:2012; EN 980:2008, EN ISO 10993-5:2009, ISO 10993-10:2010

Notified Body: SIQ, Tržaška 2, SI-1000 Ljubljana, CE 1304
EC Certificate Nr: **MDD-069**
Issued: 10.11.2016
Valid until: 30.11.2016

Ljubljana, 16.11.2016

Saving d.o.o.

Tina Samardžija

Boris Simončič