

# EC CERTIFICATE

Number: 3900729CE01

## Full Quality Assurance System

**Directive 93/42/EEC on Medical devices, Annex II excluding (4)**

(Devices in Class IIa, IIb or III)

Manufacturer:

**A.D. Integrity Applications Ltd.**

19 Ha'Yahalomim St.

POB 12163

Ashdod 7761117

Israel

For the product category(ies)

### Non-invasive glucose monitoring system for home use

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

# 0344

Documents, that form the basis of this certificate:

**Certification Notice 3900698CN, initially dated 13 March 2013**

**Addendum, initially dated 3 June 2013**

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 March 2019

Issued for the first time: 3 June 2013

Revised: 1 March 2016

Reissued: 1 March 2016

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

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# ADDENDUM

Belonging to certificate: 3900729CE01

1/1

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Non-invasive glucose monitoring system for home use

Issued to:

**A.D. Integrity Applications Ltd.**  
19 Ha'Yahalomim St.  
POB 12163  
Ashdod 7761117  
Israel

This certificate covers the following product(s):

- GlucoTrack Model DF-F (Class IIa, Indication for use: for patients of age 18 and above)

Initial date: 3 June 2013

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood.

drs. G.J. Zoetbrood  
Managing Director

A blue ink signature of ing. A.A.M. Laan.

ing. A.A.M. Laan  
Certification Manager

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