

# MANAGEMENT SYSTEM CERTIFICATE

Certificate No:  
10000364490-MSC-FINAS-LTU

Initial certification date:  
02 June 2020

Valid:  
02 June 2020 - 01 June 2023

This is to certify that the management system of

## UAB RDA Spot

Birželio 23-iosios g. 12, LT-03205, Vilnius, Lithuania

has been found to conform to the Quality Management System standard:  
**ISO 13485:2016**

This certificate is valid for the following scope:

**Development, manufacturing and sales of IVD (In-vitro diagnostics) DBS (dried blood spot) cards and kits**

Place and date:  
Espoo, 02 June 2020



For the issuing office:  
**DNV GL - Business Assurance**  
Keilasatama 5, 02150 Espoo, Finland

**Kimmo Haarala**  
Management Representative

**STATE SERVICE OF ACCREDITATION FOR HEALTH CARE ACTIVITY UNDER  
THE MINISTRY OF HEALTH**

Budget Institution, office address: 9 Juozapavičiaus str., LT-09311, Vilnius, tel. (8 5) 261 5177, fax (8 5) 212 7310, e-mail: [vaspvt@vaspvt.gov.lt](mailto:vaspvt@vaspvt.gov.lt), URL: [www.vaspvt.gov.lt](http://www.vaspvt.gov.lt).

Data is gathered and stored in the Register of Juridical Entities, code 191352247

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UAB "RDA SPOT"  
12 Birželio 23-iosios str.  
LT-03150 Vilnius

10-01-2020 No D2-275 (5.25.)  
to 07-01-2020 No S11-3  
09-01-2020 No D1-128

**REGARDING REGISTRATION OF THE SUPPLIED TO THE MARKET MEDICINE  
MEASURES (DEVICES)**

Hereby we inform that State Service of Accreditation for Health Care Activity under the Ministry of Health (hereinafter - Accreditation Service), having evaluated the provided by you on January 7, 2020 form No 2 of the Supplied to the Market Medicine Measures (Devices) (hereinafter referred to as "Form No 2") and presented together with it documents and then revised by you on January 9, 2020 Form No 2, as well as by following Item 21 of the Supplied to the Market Medicine Measures (Devices) registration order inventory, approved by order of Accreditation Service director No T1-159 'Regarding confirmation of the Supplied to the Market Medicine Measures (Devices) registration order inventory', dated 23-12-2003, made a decision to register the produced by your company the following medicine measure (device) for in vitro diagnostics:

Name of medicine measure (device)	Model	Registration number	Date of registration
In vitro diagnostics samples collection kit	RDA Spot dried blood spot samples collection kit	LT/CA01/IVD/001/20	09-01-2020

Please note that technical documentation has to be constantly reviewed and renewed, i.e. to change void legislation, standards and norms. Only safe, corresponding valid legislation and standards material and measures must be used in manufacture process. List of valid standards is announced in Lithuanian Standardization Department website <http://www.lsd.lt>.

Director

/signature/

Nora Ribokiene