

IVD MEDICAL DEVICE DECLARATION OF CONFORMITY

JSC “RDA Spot” hereby declares under its own responsibility that the following IVD medical device complies with the requirements of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Medical Device	IVD Sample Collection Card
Name	Dried Blood Spot Sample Collection Card
Model	RDA001C
Basic UDI-DI	477905472RDA001CHY
Purpose	For collection of dried blood spot samples and their delivery to the laboratory
Classification	Class A
Rule	Annex VIII Rule 5

IVD sample collection cards for the collection and delivery of dried blood spot samples to the laboratory are manufactured in accordance with the quality management system, certified according to the requirements of the ISO 13485 standard.

This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Rapolas Danilevičius, CEO

May 13, 2022. Vilnius



COMPANY WITH
QUALITY SYSTEM
CERTIFIED BY DNV GL
ISO 13485