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Responsible diagnostic. Since 1993.

ISO 9001, 13485, 15189, 17043

CE

DECLARATION OF CONFORMITY

In conformity with Annex III of the 98/79/EC Directive of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, we:

MANUFACTURER

Tody Laboratories Int. SRL
22nd Vadul Moldovei street, 1st sector, Bucharest, Romania

declare on our own responsibility that the following in vitro diagnostic medical devices

DESCRIPTION

Coronavirus (SARS-CoV-2) Antigen Rapid Test Cassette (Oral Fluid)

CODE

C61RT1040

are fulfilling the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council with regards to in vitro diagnostic medical devices, which is applicable for these products.

Classification: Other in vitro diagnostic medical devices (not included in Annex II of the 98/79/EC Directive)
Conformity assessment route: Annex III of the 98/79/EC Directive

EDMA CODE: 15 70 90 90

Applicable standards: EN ISO 9001:2008, EN ISO 13485:2012, EN ISO 13640:2002, EN ISO 14971:2012, SR EN ISO 18113-1/2:2012, EN ISO 15223:2016, EN ISO 13612:2002, EN ISO 23640:2015, EN ISO 13641:2002, EN ISO 2859/1:1999.

Place and date: Bucharest, Romania, 01.11.2020
CE marking starting date: 01.11.2020

Valeriu Todirașcu
President

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