DyonMed S.A.
Point of Care Solutions

CE DECLARATION

CE
DECLARATION OF CONFORMITY

MANUFACTURER: DYONMED S.A.
182-184, Lavriou Av.,
153 54, Glyka Nera,
Athens, Attika, Greece.

PRODUCT: **DyonCovidAg - SARS-CoV-2 Antigen Rapid Test (Immunochromatography) Cassette**

CLASSIFICATION: Other

EDMA: Coronavirus

CONFORMITY ASSESSMENT ROUTE: IVDD 98/79/EC Annex III

REGISTRATION (EOF) No:

WE, THE MANUFACTURER, ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY. WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC AND THE MINISTERIAL DECISION OF HELLENIC GOVERNMENT ΔΥ8δ/οικ.3607/892/ΦΕΚ 1060Β/10-8-2001.

ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: 98/79/EC, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612: 2002, EN ISO 23640:2015, EN 13641: 2002, EN ISO 15223-1: 2016, EN 13975:2003, EN ISO 14971:2012, EN ISO 13485: 2016, EN ISO 17511: 2003, EN 62366-1:2015, EN ISO 9001:2015.

PLACE, DATE OF ISSUE
Athens, 28-09-2020

DYONMED SA, CEO

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