



EC Declaration of Conformity

Manufacture Address: **Ergon Sutramed Srl
Via G. Gregoraci, 12
00173 Roma
Italy**

Product Information: **COVID-19 IgG/IgM Rapid test**

Product Code: **Covid-19
Covid-19/20A
Covid-19/20**

Classification: **Others
according to article 9 of directive 98/79/EC**

Conformity Assessment Route: **Annex III of Directive 98/79/EC
We hereby declare, under our sole
responsibility, that the above mentioned
products meets the provisions of the
directive 98/79/EC implemented by
Legislative Decree 332/2000**

General Applicable Directive: **Directive 98/79/EC on *in vitro* diagnostic
medical devices**

Standards Applied **All applicable harmonized standards**

Place, date of issue **Rome, 24.03.2020**

Signature of Management Representative **Mimmo Carducci**

