



## *EC Declaration of Conformity*

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

Product Information: **SARS-CoV-2 Antibody Test**

Product Code: **SARS-CoV-2**

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, MD**

