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|  | <b>CE MARKING - EC DECLARATION OF CONFORMITY</b> | <b>Doc. CQR007-4</b> |
| Mod. MCR002-0  |  | <b>Pag. 1 of 2</b>   |

for *in vitro* diagnostic medical devices covered by Directive 98/79/EC:

**Classification of the device(s):**

- device of list A annex II
- device of list B annex II
- device for self-testing not listed in annex II
- device for self-testing listed in annex II
- other device (all devices except annex II and self-testing devices)

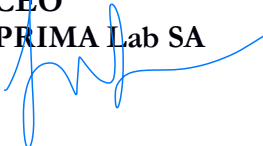
1. We, **PRIMA Lab SA**, declare that the below mentioned device is manufactured by **PRIMA Lab SA**, located in **Via Antonio Monti, 7 – CH 6828 Balerna - Switzerland**.


**PRIMA Lab SA** is exclusively responsible for this CE marking declaration of conformity. **PRIMA Lab SA** system is certified **ISO 9001:2008** and **ISO13485:2012**.

- 2. The conformity is documented by the **Technical Files**, containing all documents related to the products and to the manufacturing processes.
- 3. This device complies with all **Essential Principles and Requirements for Safety and Performance of the IVD European Directive 98/79/CE**.
- 4. **CE mark** is applied according to **Annex III of the Directive on in vitro diagnostic medical devices 98/79/EC**.

Date of Issue: *February 25th, 2020*

Federico Roveda  
**CEO**  
**PRIMA Lab SA**



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**Attachment of the CE Declaration of Conformity, devices list:**

| <b>Category</b>   | <b>Product and variants</b>        | <b>Ref.</b>       |
|---|------------------------------------|-------------------|
| rapid test for the detection of C Reactive Protein levels in whole blood, for professional use  | <b>C-Reactive Protein Test</b>     | <b>101034</b>     |
| rapid test for detection of TSH level in serum, plasma or whole blood, for professional use   | <b>Thyroid TSH Test</b>            | <b>101021</b>     |
| rapid test for detection of Ferritin level in serum, plasma or whole blood, for professional use  | <b>Iron FER Test</b>               | <b>101025</b>     |
| Helicobacter pylori rapid test in serum, plasma or whole blood, for professional use  | <b>Helicobacter pylori Test</b>    | <b>101017</b>     |
| rapid test for IgE detection in serum, plasma or whole blood, for professional use  | <b>Allergy IgE Test</b>            | <b>101018</b>     |
| rapid test for detection of immunoglobulin anti-tetanus in serum, plasma or whole blood, for professional use   | <b>Tetanus Test</b>                | <b>101092</b>     |
| rapid test for the detection of antibodies against Deamidated Gliadin (anti-DGP), IgA and IgG in blood, for the Celiac Disease screening in whole blood                                       | <b>Celiac Test</b>                 | <b>101077</b>     |
| Vaginal swab bacterial vaginosis and Trichomoniasis Test  | <b>BV TEST PRO</b>                 | <b>100114-30</b>  |
| Amniotic fluid Test detector, panty liner   | <b>AMNIOCHECK</b>                  | <b>100088-30</b>  |
| Rapid test for the semi-quantitative detection of 25-hydroxyvitamin D in human whole blood  | <b>VITAMIN D TEST</b>              | <b>101066</b>     |
| Sample collection kit for detection of 90 food intolerances in blood  | <b>FOOD INTOLERANCE TEST</b>       | <b>PL18016-90</b> |
| <i>Rapid test for the qualitative detection of IgG and IgM antibodies against COVID-19 in human whole blood, serum and plasma samples.<br/>For professional in vitro diagnostic use only.</i> | <b>COVID-19 IgG/IgM RAPID TEST</b> | <b>100061-xP</b>  |
| <i>Rapid test for the detection of Streptococcus group A <math>\beta</math>-hemolytic bacteria in pharyngeal infections. For professional use</i>   | <b>STREPA TEST</b>                 | <b>800060-xP</b>  |