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

Attachment of the CE Declaration of Conformity, devices list:

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