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 are 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.

2) **This device complies with all Essential Principles and Requirements for Safety and Performance of the IVDD European Directive 98/79/CE.**

3) **This compliance has been properly documented according to the following conformity assessment procedure:**

- ☐ Annex III excluding part 6
- ☐ Annex III including part 6
- ☒ Annex IV excluding section 4 and 6
- ☐ Annex V
- ☐ Annex VII
- ☒ Examination by a notified body
  - **Name:** mdc medical device certification GmbH
  - **Identification number:** 0483
  - **Address:** Kriegerstrasse, 6 – 70191 Stuttgard, Germany
  - **Certificate n°:** D1408400003
  - **Valid until**: 2021-02-18

4) **Expiry date: January 18th, 2021**

Balerna, June 08th, 2016

Federico Roveda
CEO
PRIMA Lab SA

PRIMA Lab SA
Via Antonio Monti 7
CH – 6828 Balerna
info@primalabsa.ch

Attachment of the CE Declaration of Conformity:

1) Device for self-testing listed in Annex II

Category	Product and variants	Ref.
Rapid Test for self-testing for PSA detection in whole blood	**Prostate-PSA Test**	**100080; 300080**