	<b><u>CE MARKING - EC DECLARATION OF CONFORMITY</u></b>	<b>Doc.CQR010-5</b>
<b>Mod. MCR001-1</b>	<b>Device for self-testing listed in annex II</b>	<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 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 the applicable Essential Principles and Requirements for Safety and Performance of the IVD 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 IV including section 4
- Annex V
- Annex VII
- Examination by a notified body
  - **Name:** mdc medical device certification GmbH
  - **Identification number:** 0483
  - **Address:** Kriegerstrasse, 6 – 70191 Stuttgart, Germany
  - **Certificate n°:** *D1408400051*
  - **Valid until:** 26-05-2025


4) **European Representative:**


**Name:** QARAD EC-REP BV

**Address:** PAS 257 2440 Geel Belgium

5) **Expiry date:** May 26<sup>th</sup>, 2025

Balerna, May 25<sup>th</sup>, 2022

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

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Attachment of the EC Declaration of Conformity (the x in the REF is a placeholder and shall indicate the number of tests included in the test kit):

Category	Product and variants	Ref.
Rapid self-test for the qualitative detection of antibodies to human immunodeficiency virus 1 and 2 (HIV1/HIV2) in whole blood	<b>HIV 1/2 Self -Test</b>	800062-1 800062-1ES 800062-1H 800062-1PB
		<i>EASY CARD® HIV SELF TEST</i>
	<i>berkeleyhealth HIV</i>	<i>890062-1</i>

