

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith grants

**PRIMA Lab SA
Via Antonio Monti 7
6828 Balerna
Switzerland**

for the scope

**HIV 1/2 SELF-TEST (REF 800062-1, 800062-1ES, 800062-1H, 800062-1PB);
EASY CARD® HIV SELF TEST (REF 870062-1);
berkeleyhealth HIV (REF 890062-1)**

the

EC Design Examination Certificate

The examination of the design of the product by mdc has proven
that the design meets the requirements according to

Annex IV – Section 4 of the Council Directive 98/79/EC

of the European Parliament and of the Council of
27 October 1998 on in vitro diagnostic medical devices.

This certificate is only valid in connection with a valid mdc certificate
according to Annex IV – excluding section 4 and 6 for the above mentioned products.

Valid from	2022-05-18
Valid until	2025-05-26
Registration no.	D1408400051
Report no.	P22-00865-237928
Stuttgart	2022-05-18


Head of Certification Body

