

Supplement to the Certificate
according to 98/79/EC, Annex IV, excluding 4 and 6
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| Manufacturer | PRIMA Lab SA |
| Certificate | No. D1408400052 Date: 2022-05-18 Testing devices for the detection of anti-HIV 1 and 2 antibodies, prostate specific antigen PSA, blood glucose and rapid self-testing devices (see attachment) |
| Products concerned | Immunochromatographic self-testing devices for detection of Group A beta-hemolytic streptococcus bacteria in throat infection |
| Intended change | New brand/commercial variant: Newfoundland Strep A Self-Test (REF 880060-x) |
| Review report no. | P22-01612-273274 |

The intended change is in compliance with the requirements of the Directive 98/79/EC.

This supplement is valid only in conjunction with the aforementioned Certificate, last modified by supplement D1408400064.

The aforementioned Certificate, last modified by supplement D1408400064, is valid only in conjunction with this supplement.

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| This supplement is valid until: | 2025-05-26 |
| Registration no.: | D1408400065 |
| Stuttgart | 2023-07-11 |


Head of Notified Body

