

Declaration of Conformity Cover Page

This cover page outlines the non-significant changes to **DoC_On Call Blood Ketone Test Strips and Control - self test_20220525** signed on **May 25th 2022**.

The following revisions to the Declaration of Conformity are deemed to be non-significant.

Version	Date	Update
01	5/25/2022	Initial release of Declaration of Conformity
02	8/16/2022	Corrected typo of V1 EC Certificate Expiration Date from 5-26-2022 to 5-26-2025

Signed this 16 day of August, 2022
in San Diego, CA USA

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Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

**We, the manufacturer, declare under our sole responsibility that the
in vitro diagnostic device:**

Device Name	REF Number
On Call® Blood Ketone Test Strips	GK134-10A, GK134-11A
On Call® Ketone Control Solution	GK124-12A

**classified for *Self-Testing* in the directive 98/79/EC,
meets all the provisions of the directive 98/79/EC on *in vitro*
diagnostic medical devices which apply to it**

**The declaration according to Annex IV of the Directive
is based on approval by the notified body
TÜV SÜD Product Service GmbH,
Ridlerstraße 65,
80339 MÜNCHEN, Germany,
notified under No. 0123 to the EC Commission.**

This declaration is valid until expiration of EC Certificate
No. V1 104507 0003 Rev. 06
Expiration Date: 2022-05-26

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 25 day of May, 2022
in San Diego, CA, USA

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Clinical Affairs

Acon Laboratories, Inc.

