ACON Laboratories, Incorporated 4108 Sorrento Valley Boulevard San Diego, CA 92121 USA

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

On-Call Advanced Blood Glucose Monitoring System (Starter Kit)

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

This declaration is according to Annex IV of the Directive and thus is based on approval by the notified body TUV Rheinland Product Safety GmbH, notified under No. 0197 to the EC Commission.

Authorized Representative: MDSS GmbH Schiffgraben 41 30175 Hannover Germany

Signed this day of for, , doog in San Diego, CA USA

Richard Lenart Regulatory Affairs Manager ACON Laboratories, Inc.



ACON Laboratories, Incorporated 4108 Sorrento Valley Boulevard San Diego, CA 92121 USA

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

On-Call Advanced Blood Glucose Meter

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

This declaration is according to Annex IV of the Directive and thus is based on approval by the notified body TUV Rheinland Product Safety GmbH, notified under No. 0197 to the EC Commission.

Authorized Representative:
MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

Signed this 2 day of April, 3009 in San Diego, CA USA

Richard Lenart

Regulatory Affairs Manager ACON Laboratories, Inc.

ACON Laboratories, Incorporated 4108 Sorrento Valley Boulevard San Diego, CA 92121 USA

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

On-Call Advanced Blood Glucose Test Strips

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

This declaration is according to Annex IV of the Directive and thus is based on approval by the notified body TUV Rheinland Product Safety GmbH, notified under No. 0197 to the EC Commission.

Authorized Representative:
MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

Signed this day of April, 2009

in San Diego, CA USA

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Richard Lenart
Regulatory Affairs Manager

ACON Laboratories, Inc.

ACON Laboratories, Incorporated 4108 Sorrento Valley Boulevard San Diego, CA 92121 USA

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

On-Call Advanced Glucose Control Solution

meets all the provisions of the directive 98/79/EC on in vitro diagnostic medical devices which apply to it

This declaration is according to Annex IV of the Directive and thus is based on approval by the notified body **TUV Rheinland Product Safety GmbH, notified under** No. 0197 to the EC Commission.

> Authorized Representative: MDSS GmbH Schiffgraben 41 30175 Hannover Germany

Signed this 2 day of April , 2009 in San Diego, CA USA

Richard Lenart

Regulatory Affairs Manager ACON Laboratories, Inc.

ACON Laboratories, Incorporated 4108 Sorrento Valley Boulevard San Diego, CA 92121 USA

We declare under our sole responsibility that the medical device:

On-Call Advanced Lancets

of Class IIA according to Annex IX of the directive 93/42/EEC,

meets all the provisions of the directive 93/42/EEC concerning medical devices which apply to it.

This declaration is according to Annex II of the Directive and thus is based on approval by the notified body **TUV Rheinland Product Safety GmbH, notified under** No. 0197 to the EC Commission.

> Authorized Representative: MDSS GmbH Schiffgraben 41 30175 Hannover Germany

Signed this 2 day of April , 2009 in San Diego, CA USA

Richard Lenart Regulatory Affairs Manager

ACON Laboratories, Inc.



ACON Laboratories, Incorporated 4108 Sorrento Valley Boulevard San Diego, CA 92121 USA

We declare under our sole responsibility that the medical device:

On-Call Advanced Lancing Device

of Class I according to Annex IX of the directive 93/42/EEC,

meets all the provisions of the directive 93/42/EEC concerning medical devices which apply to it.

This self-declaration is according to Annex VII of the Directive

Authorized Representative: MDSS GmbH Schiffgraben 41 30175 Hannover Germany

Signed this 2 day of April , 2009 in San Diego, CA USA

Richard Lenart

Regulatory Affairs Manager ACON Laboratories, Inc.