ACON Laboratories, Incorporated 10125 Mesa Rim Road San Diego, CA 92121 USA

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

Mission Plus Hb Hemoglobin Testing System

classified as others of 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

This self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
MDSS
Schiffgraben 41
30175 Hannover, Germany

Signed this day of in San Diego, CA USA

Qiyi Xie, MD, MPH

Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.

ACON Laboratories, Incorporated 10125 Mesa Rim Road San Diego, CA 92121 USA

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

Mission Plus Hb Hemoglobin Meter

classified as others of 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

This self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative: MDSS Schiffgraben 41 30175 Hannover, Germany

Signed this 40 day of in San Diego, CA USA

Qiyi Xie,/MD, MPH

Senior Staff, Regulatory Affairs & Clinical Affairs Acon Laboratories, Inc.



ACON Laboratories, Incorporated 10125 Mesa Rim Road San Diego, CA 92121 USA

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

Mission Plus Hb Hemoglobin Test Device

classified as others of 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

This self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
MDSS
Schiffgraben 41
30175 Hannover, Germany

Signed this day of sin San Diego, CA USA

Qiyi Xie, MD, MPH

Senior Staff, Regulatory Affairs & Clinical Affairs Acon Laboratories, Inc.

ACON Laboratories, Incorporated 10125 Mesa Rim Road San Diego, CA 92121 USA

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

Mission Plus Hb Hemoglobin Test Strip

classified as others of 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

This self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
MDSS
Schiffgraben 41
30175 Hannover, Germany

Signed this 4th day of Sep , 2019 in San Diego, CA USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.



ACON Laboratories, Incorporated 10125 Mesa Rim Road San Diego, CA 92121 USA

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

Mission Plus Hb Hemoglobin Control Strip

classified as others of 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

This self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:

MDSS

Schiffgraben 41
30175 Hannover, Germany

Signed this 477 day of 500, in San Diego, CA USA

Qiyi Xie, MD, MPH Senior Staff, Regulatory Affairs & Clinical Affairs Acon Laboratories, Inc.



ACON Laboratories, Incorporated 10125 Mesa Rim Road San Diego, CA 92121 USA

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

Mission Plus Hb Hemoglobin Control Device

classified as others of 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

This self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative: MDSS Schiffgraben 41 30175 Hannover, Germany

Signed this 4 day of Sep , o in San Diego, CA USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.



ACON Laboratories, Incorporated 10125 Mesa Rim Road San Diego, CA 92121 USA

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

Mission Hb Hemoglobin Control Solution

classified as others of 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

This self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
MDSS
Schiffgraben 41
30175 Hannover, Germany

Signed this 4 day of Sep, 2015 in San Diego, CA USA

Qiyi(Xie, MD, MPH

Senior Staff, Regulatory Affairs & Clinical Affairs Acon Laboratories, Inc.

