

Declaration of Conformity

We, the manufacturer, under compliance to Article 17 of regulation (EU) 2017/746, declare under our sole responsibility that the medical device:

Device Name	REF Number
Mission® U500 Urine Analyzer	U211-101, U211-111
Mission® U500 Data Transfer Kit	U221-131
Mission® Urine Analyzer Barcode Reader	U221-111
Mission® Printer Paper Rolls	U121-101

of class A according to Rule 5(b) of Annex VIII of regulation (EU) 2017/746, is in conformity with

Regulation (EU) IVDR 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

and

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and further amendments to the directive issued and in force at the date of this declaration.*

It has been demonstrated that the requirements specified in Article 4 have been met.

The materials in ACON's products are assessed in accordance with ACON's procedure for approval which uses documents and contractual agreements to evaluate compliance and approve new materials and components.*

This declaration is based on:

Manufacturer's Name: ACON Laboratories, Inc.

Manufacturer's Address: 5850 Oberlin Drive, #340 San Diego, CA 92121

Manufacturer's SRN: US-MF-000023913

Authorized Representative Name: Medical Device Safety Service GmbH

Authorized Representative Address: Schiffgraben 41, 30175 Hannover, Germany

Basic UDI-DI: 68260799999900424B

Intended Purpose of device: The U500 Urine Analyzer is intended for use in conjunction with the Urinalysis Reagent Strips for the semi-quantitative detection of the following analytes in human urine: Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Leukocytes, Ascorbic Acid, Albumin, Creatinine, and Calcium, as well as the qualitative detection of Nitrite. The instrument is intended for professional, in vitro diagnostic use only.

Signed this 20 day of May, 2022
in San Diego, CA USA





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

* This statement is based on information and data provided by third parties and may not have been verified through destructive testing or other chemical analysis.

