



This is to certify that, in accordance with the 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 (RoHS 2), Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative in accordance with the AR agreement established between MDSS GmbH and:

**Acon Laboratories, Inc.  
10125 Mesa Rim Road  
San Diego, CA 92121  
USA**

Products covered by this certificate are listed on:

Annex A dated on May 21, 2019

The manufacturer ensures that the products listed in Annex A fulfill the requirements laid down by the applicable Directives and provided MDSS GmbH with the appropriate documentation.

2019-05-21

*Elsa Villanueva · Möller*

Elsa Villanueva-Möller  
Director of Administration / Business Development  
MDSS GmbH



| Product name  | Model numbers       |
|---|---------------------|
| CentriVet GK Dual BG & Ketone Monitoring Meter      | GK114-13C           |
| CentriVet Ketone test Strips                        | GK134-10C           |
| CentriVet Blood Glucose Test Strips                 | GK134-12C           |
| Mission Printer                                     | C121-1021           |
| On Call® Bluetooth Adaptor                          | OGA-101             |
| On Call® Plus Blood Glucose Monitoring Meter        | G113-21X            |
| On Call® Plus Blood Glucose Strips                  | G133-11X            |
| Mission U120 Urine Analyzer                         | U111-1X1            |
| Mission Urine Analyzer barcode Kit                  | U221-111            |
| Mission Barcode Reader                              | U124-111            |
| Mission U120 Data transfer Kit                      | U121-131            |
| Urine Analyzer Data transfer Kit                    | U121-131            |
| Insight U120 Urine Analyzer                         | U111-1X5            |
| Insight Urine Analyzer Barcode Reader               | U124-115            |
| Insight Barcode Reader                              | U221-115            |
| Insight U120 Data transfer Kit                      | U121-135            |
| Mission Expert U120 Urine Analyzer                  | U113-1X1            |
| Mission Expert Barcode Reader                       | U223-111            |
| Mission Expert U120 Data Transfer Kit               | U123-131            |
| Insight Expert U120 Urine Analyzer                  | U113-1x5            |
| Insight Expert Barcode reader                       | U223-115            |
| Insight Expert U120 Data transfer Kit               | U123-135            |
| Urispin U120 Urine Analyzer                         | 5004001, 5004001BCR |
| Urispin U120 Barcode Reader                         | U221-113            |
| Urispin U120 Data Transfer Kit*                     | U121-133            |
| Uri-Plus 1A Urine Analyzer"                         | U111-1X3            |
| Insight U120 Smart Urine Analyzer                   | U117-1X5            |
| Insight Expert U120 Smart Urine Analyzer            | U118-1X5            |
| Mission U120 Smart Urine Analyzer                   | U117-1X1            |
| Mission U120 Smart Urine Analyzer Data Transfer Kit | U127-131            |
| Mission Expert U120 Smart Urine Analyzer            | U118-1X1            |
| On Call® EZ II Blood Glucose Meter                  | G113-15X; G113-25X  |
| On Call® Redi BGM Meter                             | G113-27X            |
| On Call® Redi BG Strip                              | G133-17X            |
| On Call® Redi II BG Strip                           | G133-1XD            |
| On Call® Plus II Blood Glucose Test Strips          | G133-1XC            |
| On Call® Plus Blood Glucose Test Strips             | G133-1XC            |
| On Call® Advance Blood Glucose Meter                | G114-1X1            |
| On Call® Advanced Blood Glucose Test Strips         | G134-1X1            |
| Insight Hemoglobin Testing System                   | C111-30X5           |
| Mission Hemoglobin Testing System                   | C111-30X1           |
| Mission Plus Hemoglobin Testing System              | C112-30X1           |
| Insight Plus Hemoglobin Testing System              | C112-30X5           |
| Mission C100 Dry Chemical Analyzer                  | C111-10X1           |
| Mission C100 Data Transfer Kit                      | C121-1031           |
| On Call® Chosen Blood Glucose Meter                 | G114-1X6            |
| On Call® Chosen Blood Glucose Test Strip            | G134-1X6            |
| On Call® Platinum Blood Glucose Meter               | G114-1X2            |

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| On Call® Platinum Blood Glucose Test Strips          | G134-1X2                     |
| Lipid Scan Lipid Profile Analyzer (CCM-111)          | C111-2023                    |
| Mission Cholesterol Monitoring System (CCM-111)      | C111-2021                    |
| Mission Ultra Cholesterol Monitoring Meter (CCM-101) | C111-5011                    |
| Mission Ultra Cholesterol CHOL Test Strips (CCS-101) | C131-5011                    |
| On Call® Vivid Blood Glucose Meter                   | G115-1X2                     |
| On Call® Vivid Blood Glucose Test Strips             | G135-1X2                     |
| D-One Blood Glucose Monitoring Meter                 | G115-109                     |
| D-One Blood Glucose Test Strips                      | G135-109; G135-119           |
| On Call® Sharp Blood Glucose Meter                   | G115-1X5                     |
| On Call® Sharp Blood Glucose Test Strips             | G135-1X5                     |
| Mission PT Coagulation Meter                         | C111-4011                    |
| Mission PT Coagulation Strip                         | C131-4011                    |
| Mission PT/INR Meter                                 | C112-4021                    |
| Mission PT/INR Test Strips                           | C132-4011                    |
| LUMIRATEK PT/INR Meter                               | LMINR-0001                   |
| LUMIRATEK PT/INR Test Strips                         | LMINR-0002; LMINR-0003       |
| On Call® Vivid Pal Blood Glucose Meter               | G115-1X7                     |
| On Call® Vivid Blood Glucose Test Strips             | G135-1X2                     |
| On Call® Extra Blood Glucose Meter                   | G115-1XH                     |
| On Call® Extra Blood Glucose Test Strips             | G135-1XH                     |
| On Call® GK Dual Blood Glucose and Ketone Meter      | GK114-13B                    |
| On Call® Ketone Test Strip                           | GK134-1XA                    |
| On Call® Plus II Blood Glucose Meter                 | G113-1XC                     |
| Mission® U500 Urine Analyzer                         | U211-1X1                     |
| Mission® U500 Data Transfer Kit                      | U221-131                     |
| Insight® U500 Urine Analyzer                         | U211-1X5                     |
| Insight® U500 Data Transfer Kit                      | U221-1X5                     |
| Mission® Expert U500 Urine Analyzer                  | U213-1X1                     |
| Mission® Expert U500 Data Transfer Kit               | U223-131                     |
| Insight® Expert U500 Urine Analyzer                  | U213-1X5                     |
| Insight® Expert U500 Data Transfer Kit               | U223-135                     |
| Uri-Plus® 5A Urine Analyzer                          | U211-1X3                     |
| Urispin® U500 Urine Analyzer                         | 5004002                      |
| Promotor™ NES-32 Nucleic Acid Extraction System      | P111-1011                    |
| On Call® A1c HbA1c Analyzer                          | G116-111                     |
| Mission Ultra Hb Hemoglobin Meter                    | C111-6011                    |
| Mission Ultra Hb Hemoglobin Test Strips              | C131-6011                    |
| Mission U120 Ultra Urine Analyzer                    | U114-1X1                     |
| Mission U120 Ultra Data Transfer Kit                 | U124-131                     |
| Insight U120 Ultra Urine Analyzer                    | U114-1X5                     |
| Insight Barcode Reader                               | U221-115                     |
| Insight U120 Ultra Data Transfer Kit                 | U124-135                     |
| Mission HA-360 3-DIFF Automatic Hematology Analyzer  | C111-9011                    |
| On Call® Extra Mobile Blood Glucose Meter            | G115-11T, G115-12T, G115-13T |
| On Call® Sure Blood Glucose Meter                    | G115-11U, G115-12U, G115-13U |
| On Call® Sure Sync Blood Glucose Meter               | G115-11W, G115-12W, G115-13W |

**Annex A May 21, 2019**  
**Manufacturer: Acon Laboratories, Inc.**



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| On Call® Sure Blood Glucose Test Strip           | G135-10U, G135-11U |
| On Call® GU Dual Blood Glucose & Uric Acid Meter | GU114-11D          |
| On Call® Blood Uric Acid Test Strip              | G134-10D, G134-11D |
| Urispin U120 Smart Urine Analyzer                | 5004003            |