

# Certificate of CE-Registration

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC and the Medical Device Directive 93/42/EEC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

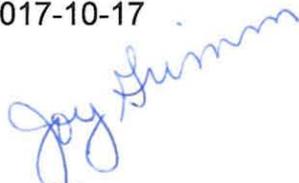
**Acon Laboratories, Inc.  
10125 Mesa Rim Road  
92121 San Diego, CA  
UNITED STATES OF AMERICA**

as stipulated and demanded by the aforementioned Directive. The European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011. The German Competent Authority is notified of the manufacturer's *in vitro* diagnostic medical devices and medical devices and has allocated registration numbers shown in:

## **Annex A dated Oct 17, 2017**

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the *in vitro* diagnostic medical devices and medical devices fulfill the applicable requirements of Directives 98/79/EC and 93/42/EEC. In compliance with German law, a safety officer has been appointed for Germany.

2017-10-17



Joy Grimm  
Senior Consultant - IVD  
MDSS GmbH

**Annex A dated Oct 17, 2017**  
**ACON Laboratories, Inc.**

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
G114-106, G114-116, G114-126, G114-136	On Call Chosen Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/026-03
G115-102, G115-112, G115-122, G115-132	On Call Vivid Blood Glucose Monitoring System	(OGM-101)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/026-03
G115-109	D-ONE Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/026-03
G115-105, G115-115, G115-125, G115-135	On Call Sharp Blood Glucose Monitoring System	(OGM-121)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/026-03
G115-107, G115-117, G115-127, G115-137	On Call Vivid Pal Blood Glucose Monitoring System	(OGM-102)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/026-03
G113-10C, G113-11C, G113-12C	On Call Plus II Blood Glucose Monitoring System	(OGM-171)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/026-03



**Annex A dated Oct 17, 2017  
ACON Laboratories, Inc.**

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
GK114-13B	On Call GK Dual Blood Glucose & Ketone Monitoring System	(OGM-161)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/026-03
G115-10H, G115-11H, G115-12H, G115-13H	On Call Extra Blood Glucose Monitoring System	(OGM-191)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/026-03
G134-106, G134-116	On Call Chosen Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/025-03
G135-102, G135-112	On Call Vivid Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/025-03
G135-109, G135-119	D-ONE Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/025-03
G135-105, G135-115	On Call Sharp Blood Glucose Test Strips	(OGS-121)	11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/025-03
G133-11C, G133-10C	On Call Plus II Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/025-03
G135-10H, G135-11H	On Call Extra Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/025-03
G124-126	On Call Chosen Glucose Control Solution		11 70 01 50	Calibrators and Controls (Blood Test Strips)	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/024-04
G125-122	On Call Vivid Glucose Control Solution		11 70 01 50	Calibrators and Controls (Blood Test Strips)	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/024-04



**Annex A dated Oct 17, 2017  
ACON Laboratories, Inc.**

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
G125-129	D-ONE Glucose Control Solution		11 70 01 50	Calibrators and Controls (Blood Test Strips)	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/024-04
G125-125	On Call Sharp-Glucose Control Solution		11 70 01 50	Calibrators and Controls (Blood Test Strips)	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/024-04
G123-12C	On Call Plus II Glucose Control Solution		11 70 01 50	Calibrators and Controls (Blood Test Strips)	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/024-04
G124-12A	On Call Ketone Control Solution		11 70 01 50	Calibrators and Controls (Blood Test Strips)	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/024-04
G125-12H	On Call Extra Glucose Control Solution		11 70 01 50	Calibrators and Controls (Blood Test Strips)	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/024-04
GK134-10A, GK134-11A	On Call Blood Ketone Test Strips		11 70 01 08	Ketone Test Strips	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/008-02
G113-111, G113-112, G113-211, G113-214, G113-215, G113-216	On Call™ Plus Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/060-04
G114-101, G114-111, G114-121, G114-131	On Call™ Advanced Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/060-04



**Annex A dated Oct 17, 2017  
ACON Laboratories, Inc.**

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
G113-171, G113-271, G113-274	On Call Redi Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/060-04
G113-151, G113-251, G113-152, G113-251, G113-254	On Call EZ II Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/060-04
G114-102, G114-112, G114-122, G114-132	On Call Platinum Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/060-04
G133-11x	On Call™ Plus Blood Glucose Test Strips		11 70 01 01 00	Glucose Test Strips	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/059-03
G134-101, G 134-111	On Call™ Advanced Blood Glucose Test Strips		11 70 01 01 00	Glucose Test Strips	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/059-03
G134-102, G134-112	On Call Platinum Blood Glucose Test Strips		11 70 01 01 00	Glucose Test Strips	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/059-03
G133-10D, G133-11D	On Call Redi II Blood Glucose Test Strips		11 70 01 01 00	Glucose Test Strips	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/059-03
G123-311	On Call™ Plus Blood Glucose Control Solution		11 70 01 50 00	Calibrators and controls (Blood Test Strips)	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/058-03

**Annex A dated Oct 17, 2017**  
**ACON Laboratories, Inc.**

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
G124-121	On Call™ Advanced Glucose Control Solution		11 70 01 50 00	Calibrators and controls (Blood Test Strips)	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/058-03
G123-371	On Call Redi Glucose Control Solution		11 70 01 50 00	Calibrators and controls (Blood Test Strips)	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/058-03
G124-122	On Call Platinum Glucose Control Solution		11 70 01 50 00	Calibrators and controls (Blood Test Strips)	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/058-03
G123-12D	On Call Redi II Glucose Control Solution		11 70 01 50 00	Calibrators and controls (Blood Test Strips)	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/058-03
I231-1101	Foresight Toxoplasma IgM EIA Test Kit		15 05 01 06 00	Toxoplasma Antibody IgM	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/041-03
I231-1102	Incontrol Toxoplasma IgM EIA Test Kit		15 05 01 06 00	Toxoplasma Antibody IgM	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/041-03
I231-1091	Foresight Toxoplasma IgG EIA Test Kit		15 05 01 05 00	Toxoplasma Antibody IgG	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/040-03
I231-1092	Incontrol Toxoplasma IgG EIA Test Kit		15 05 01 05 00	Toxoplasma Antibody IgG	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/040-03
I231-1121	Foresight Rubella IgM EIA Test Kit		15 04 01 06 00	Rubella Virus IgM	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/039-03
I231-1122	Incontrol Rubella IgM EIA Test Kit		15 04 01 06 00	Rubella Virus IgM	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/039-03
I231-1111	Foresight Rubella IgG EIA Test Kit		15 04 01 05 00	Rubella Virus IgG	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/038-03
I231-1112	Incontrol Rubella IgG EIA Test Kit		15 04 01 05 00	Rubella Virus IgG	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/038-03



**Annex A dated Oct 17, 2017**  
**ACON Laboratories, Inc.**

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
I231-1141	Foresight CMV IgM EIA Test Kit		15 04 02 06 00	CMV IgM	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/037-03
I231-1142	Incontrol CMV IgM EIA Test Kit		15 04 02 06 00	CMV IgM	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/037-03
I231-1131	Foresight CMV IgG EIA Test Kit		15 04 02 05 00	CMV IgG	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/036-03
I231-1132	Incontrol CMV IgG EIA Test Kit		15 04 02 05 00	CMV IgG	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/036-03
U031-XX1	Mission® Urinalysis Reagent Strips		11 70 02 02 00	Urine Multi-constituent Test Strips	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/048-03
U031-XX5	Insight® Urinalysis Reagent Strips		11 70 02 02 00	Urine Multi-constituent Test Strips	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/048-03
49110000xx	Blaas Check		11 70 02 02 00	Urine Multi-constituent Test Strips	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/048-03
4911000xxx	Urineweginfectie Thuistest Totaal Check Thuistest Voor urine		11 70 02 02 00	Urine Multi-constituent Test Strips	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/048-03
U031-XX1	Mission® Urinalysis Reagent Strips		11 70 02 01 00	Urine Single Test Strips (incl. Tablets)	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/047-03
U031-XX5	Insight® Urinalysis Reagent Strips		11 70 02 01 00	Urine Single Test Strips (incl. Tablets)	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/047-03
49110000xx	Blaas Check		11 70 02 01 00	Urine Single Test Strips (incl. Tablets)	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/047-03
4911000xxx	Urineweginfectie Thuistest Totaal Check Thuistest Voor urine		11 70 02 01 00	Urine Single Test Strips (incl. Tablets)	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/047-03
U031-021	Mission® UTI Urinary Tract Infection Test Strips		14 01 07 02 00	Urine Screening Manual - Strips, etc.	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/046-03

**Annex A dated Oct 17, 2017**

**ACON Laboratories, Inc.**

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
U031-025	Insight® UTI Urinary Tract Infection Test Strips		14 01 07 02 00	Urine Screening Manual - Strips, etc.	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/046-03
I231-2031	Foresight Total PSA EIA Test Kit		12 03 01 32	Total Prostatic Specific Antigen	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/015-03
I231-2032	In control Total PSA EIA Test Kit		12 03 01 32	Total Prostatic Specific Antigen	Annex II - List B	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/015-03
C111-4011	Mission® PT Coagulation Monitoring System	(CCM-121)	23 07 10 02	Coagulation Hardware +accessories + consumables + software	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/064-03
C112-4021	Mission® PT/INR Monitoring System	(model CCM-151)	23 07 10 02	Coagulation Hardware +accessories + consumables + software	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/064-03
LMINR-0001	LUMIRATEK PT/INR Monitoring System		23 07 10 02	Coagulation Hardware +accessories + consumables + software	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/064-03
C131-4011	Mission® PT Coagulation Test Strips	(CCS-121)	13 02 70 01 00	Prothrombin Time Rapid Test	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/063-03
C132-4011	Mission® PT/INR Test Strips	(CCS-151)	13 02 70 01 00	Prothrombin Time Rapid Test	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/063-03
LMINR-0002; LMINR-0003	LUMIRATEK PT/INR Test Strips		13 02 70 01 00	Prothrombin Time Rapid Test	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/063-03



**Annex A dated Oct 17, 2017**  
**ACON Laboratories, Inc.**

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
C121-4011	Mission® PT Coagulation Control Solution		13 02 70 50	Controls Rapid tests	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/062-03
C122-4011	Mission® PT/INR Control Solution		13 02 70 50	Controls Rapid tests	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/062-03
LMINR-0004	LUMIRATEK PT/INR Control Solution		13 02 70 50	Controls Rapid tests	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/062-03
C111-2021	Mission® Cholesterol Monitoring System	(CCM-111)	21 07 10 03	RT_CC Hardware + accessories + consumables + software	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/070-02
C111-5011	Mission® Ultra Cholesterol Monitoring System	(CCM-101)	21 07 10 03	RT_CC Hardware + accessories + consumables + software	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/070-02
C111-2023	LipidScan Lipid Profile Analyzer	(CCM-111)	21 07 10 03	RT_CC Hardware + accessories + consumables + software	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/070-02
C131-2011	Mission® Cholesterol CHOL Total Cholesterol Test Device	(CCS-111)	11 70 01 02	Cholesterol Test Strips	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/069-03
C131-5011	Mission® Ultra Cholesterol CHOL Total Cholesterol Test Strips	(CCS-101)	11 70 01 02	Cholesterol Test Strips	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/069-03
C131-2043	LipidScan Lipid Profile Test Device Total Cholesterol (CHOL)	(CCS-111)	11 70 01 02	Cholesterol Test Strips	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/069-03



**Annex A dated Oct 17, 2017  
ACON Laboratories, Inc.**

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
C131-2021	Mission® Cholesterol TRIG Triglyceride Test Device	(CCS-112)	11 70 01 05	Triglyceride Test Strips	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/068-03
C131-2023	LipidScan Lipid Profile Test Device Triglycerides (TRIG)	(CCS-112)	11 70 01 05	Triglyceride Test Strips	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/068-03
C131-2031	Mission® Cholesterol HDL High Density Lipoprotein Test Device	(CCS-113)	11 70 01 03	HDL Test Strips	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/067-03
C131-2033	LipidScan Lipid Profile Test Device High Density Lipid Protein (HDL)	(CCS-113)	11 70 01 03	HDL Test Strips	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/067-03
C131-2041	Mission® Cholesterol 3-in-1 Lipid Panel Test Device	(CCS-114)	11 70 01 30	Multiple parameter blood test	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/066-03
C131-2043	LipidScan Lipid Profile Test Device Combo Lipid Profile	(CCS-114)	11 70 01 30	Multiple parameter blood test	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/066-03
C121-2021	Mission® Cholesterol Control Device		11 70 01 50	Calibrators and Controls (Blood Test Strips)	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/065-03
C121-5011	Mission® Ultra Cholesterol Control Solution		11 70 01 50	Calibrators and Controls (Blood Test Strips)	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/065-03
C121-2011	Mission® Cholesterol Control Solution		11 70 01 50	Calibrators and Controls (Blood Test Strips)	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/065-03

**Annex A dated Oct 17, 2017  
ACON Laboratories, Inc.**

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
C121-2023	LipidScan Lipid Profile Control Device		11 70 01 50	Calibrators and Controls (Blood Test Strips)	Self Test	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/065-03
U111-101, U111-111	Mission® U120 Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U221-111	Mission® Urine Analyzer Barcode Reader		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U121-131	Mission® U120 Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U121-101	Mission® Printer Paper Rolls		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U111-105, U111-115	Insight® U120 Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U221-115	Insight® Barcode Reader		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U121-135	Insight® U120 Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U121-105	Insight® Printer Paper Rolls		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U113-101, U113-111	Mission® Expert U120 Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02



## Annex A dated Oct 17, 2017

## ACON Laboratories, Inc.

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
U223-111	Mission® Expert Barcode Reader		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U123-131	Mission® Expert U120 Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U113- 105, U113-115	Insight® Expert U120 Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U223-115	Insight® Expert Barcode Reader		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U123-135	Insight® Expert U120 Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U211-101, U211-111	Mission® U500 Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U221-131	Mission® U500 Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U211-105, U211-115	Insight® U500 Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U221-135	Insight® U500 Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U213-101, U213-111	Mission® Expert U500 Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02

**Annex A dated Oct 17, 2017  
ACON Laboratories, Inc.**

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
U223-131	Mission® Expert U500 Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U213-105, U123-115	Insight® Expert U500 Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U223-135	Insight® Expert U500 Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U114-101, U114-111	Mission® U120 Ultra Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U124-111	Mission® Barcode Reader		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U124-131	Mission® U120 Ultra Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U114-105, U114-115	Insight® U120 Ultra Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U124-115	Insight® Urine Analyzer Barcode Reader		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U124-135	Insight® U120 Ultra Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
5004001, 5004001BCR	Urispin U120 Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02



**Annex A dated Oct 17, 2017**  
**ACON Laboratories, Inc.**

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
U211-1X3	Urispin U500 Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
5004002	Urispin U500 Urine Analyzer (SPINREACT)		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U221-113	Urinspin Urine Analyzer Barcode Reader		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U111-1X3	Uri-Plus 1A Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U211-1X3	Uri-Plus 5A Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U121-103	Urinspin Pinter Paper Rolls		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
C111-5011	Mission® Ultra Cholesterol Monitoring System		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
C111-2021	Mission® Cholesterol Monitoring System	(CCM-111)	21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
C111-2023	LipidScan Lipid Profile Analyzer	(CCM-111)	21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
G116-111	On Call® A1c HbA1c Analyzer	(OGM-141)	21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02



**Annex A dated Oct 17, 2017  
ACON Laboratories, Inc.**

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
U118-101, U118-111	Mission® Expert U120 Smart Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U128-131	Mission® Expert U120 Smart Urine Analyzer Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U118-105, U118-115	Insight® Expert U120 Smart Urine Analyser		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U128-135	Insight® Expert U120 Smart Urine Analyser Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U117-101, U117-111	Mission® U120 Smart Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U127-131	Mission® U120 Smart Urine Analyzer Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U117-105, U117-115	Insight® U120 Smart Urine Analyser		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U127-135	Insight® U120 Smart Urine Analyser Data Transfer Kit		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U123-101	Mission® Expert Printer Paper Rolls		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02
U123-105	Insight® U120 Expert Printer Paper Rolls		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-02



**Annex A dated Oct 17, 2017**  
**ACON Laboratories, Inc.**

REF	Notified Device Names	optional informa-tion (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
C131-5011	Mission® Ultra CHOL Total Cholesterol Test Strips		11 70 01 02	Cholesterol Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/018-01
C131-2011	Mission® CHOL Total Cholesterol Test Strips	(CCS-111)	11 70 01 02	Cholesterol Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/018-01
C131-2013	LipidScan Lipid Profile Test Device Total Cholesterol (CHOL)	(CCS-111)	11 70 01 02	Cholesterol Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/018-01
C131-2021	Mission® Cholesterol TRIG Triglyceride Test Device	(CCS-112)	11 70 01 05	Triglyceride Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/013-01
C131-2023	LipidScan Lipid Profile Test Device Triglycerides (TRIG)	(CCS-112)	11 70 01 05	Triglyceride Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/013-01
C131-2031	Mission® Cholesterol HDL High Density Lipoprotein Test Device	(CCS-113)	11 70 01 03	HDL Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/013-01
C131-2033	LipidScan Lipid Profile Test Device High Density Lipid Protein (HDL)	(CCS-113)	11 70 01 03	HDL Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/013-01
C131-2041	Mission® Cholesterol 3-in-1 Lipid Panel Test Device	(CCS-114)	11 70 01 30	Multiple parameter blood test	"Other"	N/A	DE/CA09/0170/A10/IVD/011-01
C131-2043	LipidScan Lipid Profile Test Device Combo Lipid Profile	(CCS-114)	11 70 01 30	Multiple parameter blood test	"Other"	N/A	DE/CA09/0170/A10/IVD/011-01



**Annex A dated Oct 17, 2017**  
**ACON Laboratories, Inc.**

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
C121-5011	Mission® Ultra Cholesterol Control Solution		11 70 01 50	Calibrators and Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-01
C121-2011	Mission® Cholesterol Control Solution		11 70 01 50	Calibrators and Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-01
C121-2021	Mission® Cholesterol Control Device		11 70 01 50	Calibrators and Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-01
C121-2023	LipidScan Lipid Profile Control Device		11 70 01 50	Calibrators and Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-01
U031-XX1	Mission® Urinalysis Reagent Strips		11 70 02 01 00	Urine Single Test Strips (incl. Tablets)	"Other"	N/A	DE/CA09/0170/A10/IVD/031-01
U031-XX5	Insight® Urinalysis Reagent Strips		11 70 02 01 00	Urine Single Test Strips (incl. Tablets)	"Other"	N/A	DE/CA09/0170/A10/IVD/031-01
U033-XX1, U034-XX1	Mission® Expert Urinalysis Reagent Strips		11 70 02 01 00	Urine Single Test Strips (incl. Tablets)	"Other"	N/A	DE/CA09/0170/A10/IVD/031-01
U033-XX5, U034-XX5	Insight® Expert Urinalysis Reagent Strips		11 70 02 01 00	Urine Single Test Strips (incl. Tablets)	"Other"	N/A	DE/CA09/0170/A10/IVD/031-01



**Annex A dated Oct 17, 2017**

**ACON Laboratories, Inc.**

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
U031-XX1	Mission® Urinalysis Reagent Strips		11 70 02 02 00	Urine Multi-constituent Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/057-01
U031-XX5	Insight® Urinalysis Reagent Strips		11 70 02 02 00	Urine Multi-constituent Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/057-01
U031-XX3	MiTest Urinary Urinalysis Reagent Strips		11 70 02 02 00	Urine Multi-constituent Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/057-01
U033-XX1, U034-XX1	Mission® Expert Urinalysis Reagent Strips		11 70 02 02 00	Urine Multi-constituent Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/057-01
U033-XX5, U034-XX5	Insight® Expert Urinalysis Reagent Strips		11 70 02 02 00	Urine Multi-constituent Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/057-01
U021-011, U021-021, U021-031 U021-015, U021-025, U021-035 U021-071, U021-081, U021-091	Mission® Liquid Urine Control		11 50 02 06	Urine Control	"Other"	N/A	DE/CA09/0170/A10/IVD/035-01
U021-075, U021-085, U021-095	Insight® Liquid Urine Control		11 50 02 06	Urine Control	"Other"	N/A	DE/CA09/0170/A10/IVD/035-01
U021-041, U021-051, U021-061	Mission® Liquid Diptube Urine Control		11 50 02 06	Urine Control	"Other"	N/A	DE/CA09/0170/A10/IVD/035-01
U021-045, U021-055, U021-065	Insight® Liquid Diptube Urine Control		11 50 02 06	Urine Control	"Other"	N/A	DE/CA09/0170/A10/IVD/035-01
	Mission® Dry Strip Urine Control		11 50 02 06	Urine Control	"Other"	N/A	DE/CA09/0170/A10/IVD/035-01
	Insight® Dry Strip Urine Control		11 50 02 06	Urine Control	"Other"	N/A	DE/CA09/0170/A10/IVD/035-01



**Annex A dated Oct 17, 2017**

**ACON Laboratories, Inc.**

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
C111-3011, C111-3021, C111-3031 C111-3015, C111-3025, C111-3035	Mission® Hb Hemoglobin Testing System		23 07 10 00	RT_HHC Hardware + dedicated accessories or software	"Other"	N/A	DE/CA09/0170/A10/IVD/034-02
C112-3011, C112-3021, C112-3031	Insight® Hb Hemoglobin Testing System		23 07 10 00	RT_HHC Hardware + dedicated accessories or software	"Other"	N/A	DE/CA09/0170/A10/IVD/034-02
C121-3021	Mission® Plus Hb Hemoglobin Testing System		23 07 10 00	RT_HHC Hardware + dedicated accessories or software	"Other"	N/A	DE/CA09/0170/A10/IVD/034-02
C111-6011	Mission® Hb Data Transfer Kit		23 07 10 00	RT_HHC Hardware + dedicated accessories or software	"Other"	N/A	DE/CA09/0170/A10/IVD/034-02
C111-6011	Mission Ultra Hemoglobin Testing System	(CCM-141)	23 07 10 00	RT_HHC Hardware + dedicated accessories or software	"Other"	N/A	DE/CA09/0170/A10/IVD/034-02
C131-3011, C131-3021	Mission® Hb Hemoglobin Test Strips		13 01 70 01 00	Haemoglobin (Hb)	"Other"	N/A	DE/CA09/0170/A10/IVD/033-02
C131-3015	Insight® Hb Hemoglobin Test Strips		13 01 70 01 00	Haemoglobin (Hb)	"Other"	N/A	DE/CA09/0170/A10/IVD/033-02
C132-3011, C132-3031	Mission® Plus Hemoglobin Test Strips		13 01 70 01 00	Haemoglobin (Hb)	"Other"	N/A	DE/CA09/0170/A10/IVD/033-02
C132-3021, C132-3041	Mission® Plus Hemoglobin Test Devices		13 01 70 01 00	Haemoglobin (Hb)	"Other"	N/A	DE/CA09/0170/A10/IVD/033-02
C131-6011	Mission Ultra Hemoglobin Test Strips	(CCS-141)	13 01 70 01 00	Haemoglobin (Hb)	"Other"	N/A	DE/CA09/0170/A10/IVD/033-02



**Annex A dated Oct 17, 2017  
ACON Laboratories, Inc.**

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
C121-3031	Mission® Hb Hemoglobin Control Strip		13 01 50 04 00	Haemoglobin Control	"Other"	N/A	DE/CA09/0170/A10/IVD/032-02
C121-3035	Insight® Hb Hemoglobin Control Strip		13 01 50 04 00	Haemoglobin Control	"Other"	N/A	DE/CA09/0170/A10/IVD/032-02
C122-3011	Mission® Plus Hb Hemoglobin Control Strip	(Optic Check)	13 01 50 04 00	Haemoglobin Control	"Other"	N/A	DE/CA09/0170/A10/IVD/032-02
C122-3021	Mission® Plus Hb Hemoglobin Control Device	(Optic Check)	13 01 50 04 00	Haemoglobin Control	"Other"	N/A	DE/CA09/0170/A10/IVD/032-02
C121-3091	Mission® Hb Hemoglobin Control Solution		13 01 50 04 00	Haemoglobin Control	"Other"	N/A	DE/CA09/0170/A10/IVD/032-02
C121-6011	Mission Ultra Hemoglobin Control Solution		13 01 50 04 00	Haemoglobin Control	"Other"	N/A	DE/CA09/0170/A10/IVD/032-02
C111-1011	Mission® C 100 Dry Chemistry Analyzer		21 01 10 01	CH Hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/023-01
C121-1011	Mission® Optical Check Strips		21 01 10 01	CH Hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/023-01
C121-1031	Mission® C 100 Data Transfer Kit		21 01 10 01	CH Hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/023-01
C131-1011	Mission® ALT Alanine Aminotransferase Test Strips		11 01 01 03 00	Alanine Amino-Transferase	"Other"	N/A	DE/CA09/0170/A10/IVD/022



**Annex A dated Oct 17, 2017**  
**ACON Laboratories, Inc.**

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
C121-1051	Mission® ALT Control		11 50 02 90	Other Specific Control Sera (CC)	"Other"	N/A	DE/CA09/0170/A10/IVD/016-01
I231-4031	Foresight FSH EIA Test Kit		12 05 01 04	Follicle Stimulating Hormone	"Other"	N/A	DE/CA09/0170/A10/IVD/014
I231-4032	Incontrol FSH EIA Test Kit		12 05 01 04	Follicle Stimulating Hormone	"Other"	N/A	DE/CA09/0170/A10/IVD/014
I231-4021	Foresight LH EIA Test Kit		12 05 01 05	Luteinising Hormone	"Other"	N/A	DE/CA09/0170/A10/IVD/021
I231-4022	Incontrol LH EIA Test Kit		12 05 01 05	Luteinising Hormone	"Other"	N/A	DE/CA09/0170/A10/IVD/021
I231-4041	Foresight PRL EIA Test Kit		12 05 01 08	Prolactin	"Other"	N/A	DE/CA09/0170/A10/IVD/020
I231-4042	Incontrol PRL EIA Test Kit		12 05 01 08	Prolactin	"Other"	N/A	DE/CA09/0170/A10/IVD/020
I231-4011	Foresight Rapid HCG EIA Test Kit		12 05 02 05	Human Chorionic Gonadotropin Total	"Other"	N/A	DE/CA09/0170/A10/IVD/019-01
I231-4012	Incontrol Rapid HCG EIA Test Kit		12 05 02 05	Human Chorionic Gonadotropin Total	"Other"	N/A	DE/CA09/0170/A10/IVD/019-01
I231-4051	Foresight HCG EIA Test Kit	(quantitative)	12 05 02 05	Human Chorionic Gonadotropin Total	"Other"	N/A	DE/CA09/0170/A10/IVD/019-01
I231-4052	Incontrol HCG EIA Test Kit	(quantitative)	12 05 02 05	Human Chorionic Gonadotropin Total	"Other"	N/A	DE/CA09/0170/A10/IVD/019-01
C121-3081	Mission® Capillary Transfer Tubes		15-192	Tube, Capillary	I	N/A	DE/CA09/0170/A10/001-01
C121-3085	Insight® Capillary Transfer Tubes		15-192	Tube, Capillary	I	N/A	DE/CA09/0170/A10/001-01



**Annex A dated Oct 17, 2017**  
**ACON Laboratories, Inc.**

REF	Notified Device Names	optional informa-tion (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
G123-191	Testamed Diabetes Care Lancets		10-440	Lancets, Blood	lia	0123 / G1 13 12 80997 004-06.09.2018	DE/CA09/0170/A10/003-01
G123-191	Testamed Diabetes Care Soft Lancets		10-440	Lancets, Blood	lia	0123 / G1 13 12 80997 004-06.09.2018	DE/CA09/0170/A10/003-01
C121-3041	Mission® Lancets		10-440	Lancets, Blood	lia	123 / G1 13 12 80997 004-06.09.2018	DE/CA09/0170/A10/003-01
G123-7B1	On Call Safety Lancets I		10-440	Lancets, Blood	lia	123 / G1 13 12 80997 004-06.09.2018	DE/CA09/0170/A10/003-01
C121-3061	Mission® Safety Lancets I		10-440	Lancets, Blood	lia	123 / G1 13 12 80997 004-06.09.2018	DE/CA09/0170/A10/003-01
N/A (kit component)	D-One Lancets		10-440	Lancets, Blood	lia	123 / G1 13 12 80997 004-06.09.2018	DE/CA09/0170/A10/003-01
G124-10A	On Call Lancets		10-440	Lancets, Blood	lia	123 / G1 13 12 80997 004-06.09.2018	DE/CA09/0170/A10/003-01
G123-291	Testamed Diabetes Care Lancing Device		16-380	Lancing Devices, Blood	I	N/A	DE/CA09/0170/A10/002-01
C121-3051	Mission® Lancing Device		16-380	Lancing Devices, Blood	I	N/A	DE/CA09/0170/A10/002-01
N/A (kit component)	D-One Lancing Device		16-380	Lancing Devices, Blood	I	N/A	DE/CA09/0170/A10/002-01
G124-11A	On Call Lancing Device		16-380	Lancing Devices, Blood	I	N/A	DE/CA09/0170/A10/002-01
G124-17A	On Call GenTouch Lancing Device		16-380	Lancing Devices, Blood	I	N/A	DE/CA09/0170/A10/002-01
1231-1192	Incontrol HSV 1/2 IgG EIA Test Kit		15 04 03 05 00	HSV IgG	"Other"	N/A	DE/CA09/0170/A10/IVD/053-01
1231-1191	Foresight HSV 1/2 IgG EIA Test Kit		15 04 03 05 00	HSV IgG	"Other"	N/A	DE/CA09/0170/A10/IVD/053-01



**Annex A dated Oct 17, 2017  
ACON Laboratories, Inc.**

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
1231-1202	Incontrol HSV 1/2 IgM EIA Test Kit		15 04 03 06 00	HSV IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/050-01
1231-1201	Foresight HSV 1/2 IgM EIA Test Kit		15 04 03 06 00	HSV IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/050-01
1231-1152	Incontrol HSV 1 IgG EIA Test Kit		15 04 03 08 00	HSV 1 IgG	"Other"	N/A	DE/CA09/0170/A10/IVD/052-01
1231-1151	Foresight HSV 1 IgG EIA Test Kit		15 04 03 08 00	HSV 1 IgG	"Other"	N/A	DE/CA09/0170/A10/IVD/052-01
1231-1172	Incontrol HSV 2 IgG Test Kit		15 04 03 11 00	HSV 2 IgG	"Other"	N/A	DE/CA09/0170/A10/IVD/051-01
1231-1171	Foresight HSV 2 IgG Test Kit		15 04 03 11 00	HSV 2 IgG	"Other"	N/A	DE/CA09/0170/A10/IVD/051-01
1231-1182	Incontrol HSV 2 IgM EIA Test Kit		15 04 03 12 00	HSV 2 IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/049-01
1231-1181	Foresight HSV 2 IgM EIA Test Kit		15 04 03 12 00	HSV 2 IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/049-01
1231-1162	Incontrol HSV 1 IgM EIA Test Kit		15 04 03 09 00	HSV 1 IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/010-01
1231-1161	Foresight HSV 1 IgM EIA Test Kit		15 04 03 09 00	HSV 1 IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/010-01
1031-1011	Foresight Allergen Test Kit		12 02 01 06	Immunoglobulin E - Screen	"Other"	N/A	DE/CA09/0170/A10/IVD/009
1231-2011	Foresight AFP EIA Kit		12 03 90 01 00	Alphafetoprotein	"Other"	N/A	DE/CA09/0170/A10/IVD/061-01
1231-2012	Incontrol AFP EIA Kit		12 03 90 01 00	Alphafetoprotein	"Other"	N/A	DE/CA09/0170/A10/IVD/061-01

## Annex A dated Oct 17, 2017

## ACON Laboratories, Inc.

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
C031-021	Mission® Saliva Alcohol Test Strip		12 09 02 07 00	Ethanol (Alcohol)	"Other"	N/A	DE/CA09/0170/A10/IVD/056-01
C031-025	Insight® Saliva Alcohol Test Strip		12 09 02 07 00	Ethanol (Alcohol)	"Other"	N/A	DE/CA09/0170/A10/IVD/056-01
C031-011, C031-031	Mission® Breath Alcohol Detector		12 09 02 07 00	Ethanol (Alcohol)	"Other"	N/A	DE/CA09/0170/A10/IVD/056-01
C031-015, C031-035	Insight® Breath Alcohol Detector		12 09 02 07 00	Ethanol (Alcohol)	"Other"	N/A	DE/CA09/0170/A10/IVD/056-01
I231-1231	Foresight H. pylori Antigen EIA Test Kit		15 01 04 01 00	H. Pylori Antigen Detection	"Other"	N/A	DE/CA09/0170/A10/IVD/055-01
I231-1232	Incontrol H. pylori Antigen EIA Test Kit		15 01 04 01 00	H. Pylori Antigen Detection	"Other"	N/A	DE/CA09/0170/A10/IVD/055-01
I231-1042	Incontrol Total Syphilis Antibody EIA Test Kit		15 01 03 03 00	Syphilis Antibody Assays Total	"Other"	N/A	DE/CA09/0170/A10/IVD/054-01
I231-1041	Foresight Total Syphilis Antibody EIA Test Kit		15 01 03 03 00	Syphilis Antibody Assays Total	"Other"	N/A	DE/CA09/0170/A10/IVD/054-01
I231-1211	Foresight HEV IgM EIA Kit		15 02 05 06 00	HEV Antibody IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/044-01
I231-1212	Incontrol HEV IgM EIA Kit		15 02 05 06 00	HEV Antibody IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/044-01
I231-3011	Foresight TSH EIA Kit		12 04 01 11 00	Thyroid Stimulating Hormone	"Other"	N/A	DE/CA09/0170/A10/IVD/045-01
I231-3012	Incontrol TSH EIA Kit		12 04 01 11 00	Thyroid Stimulating Hormone	"Other"	N/A	DE/CA09/0170/A10/IVD/045-01

**Annex A dated Oct 17, 2017  
ACON Laboratories, Inc.**

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
1231-2021	Foresight CEA EIA Kit		12 03 01 31 00	Carcinoembryonic Antigen	"Other"	N/A	DE/CA09/0170/A10/IVD/043-01
1231-2022	Incontrol CEA EIA Kit		12 03 01 31 00	Carcinoembryonic Antigen	"Other"	N/A	DE/CA09/0170/A10/IVD/043-01
1231-1241	Foresight H. pylori IgG EIA Test Kit		15 01 04 03 00	H. Pylori Antibody Assay	"Other"	N/A	DE/CA09/0170/A10/IVD/042-01
1231-1242	InControl H. pylori IgG EIA Test Kit		15 01 04 03 00	H. Pylori Antibody Assay	"Other"	N/A	DE/CA09/0170/A10/IVD/042-01
1231-3051	Foresight Free T3 EIA Test Kit		12 04 01 01 00	Free Triiodothyronine	"Other"	N/A	DE/CA09/0170/A10/IVD/029-01
1231-3052	Incontrol Free T3 EIA Test Kit		12 04 01 01 00	Free Triiodothyronine	"Other"	N/A	DE/CA09/0170/A10/IVD/029-01
1231-3031	Foresight Free T4 EIA Test Kit		12 04 01 02 00	Free Thyroxine	"Other"	N/A	DE/CA09/0170/A10/IVD/028-01
1231-3032	Incontrol Free T4 EIA Test Kit		12 04 01 02 00	Free Thyroxine	"Other"	N/A	DE/CA09/0170/A10/IVD/028-01
1231-3041	Foresight Total T3 EIA Test Kit		12 04 01 05 00	Triiodothyronine	"Other"	N/A	DE/CA09/0170/A10/IVD/027-01
1231-3042	Incontrol Total T3 EIA Test Kit		12 04 01 05 00	Triiodothyronine	"Other"	N/A	DE/CA09/0170/A10/IVD/027-01
1231-3021	Foresight Total T4 EIA Test Kit		12 04 01 07 00	Thyroxine	"Other"	N/A	DE/CA09/0170/A10/IVD/030-01
1231-3022	Incontrol Total T4 EIA Test Kit		12 04 01 07 00	Thyroxine	"Other"	N/A	DE/CA09/0170/A10/IVD/030-01

**Annex A dated Oct 17, 2017  
ACON Laboratories, Inc.**

REF	Notified Device Names	optional informa-tion (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
P121-1101	Promotor™ Nucleic Acid (DNA) Extraction Kit		15 90 40 01	Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus	"Other"	N/A	DE/CA09/0170/A10/IVD/007-01
P121-1121	Promotor™ Nucleic Acid (RNA) Extraction Kit		15 90 40 01	Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus	"Other"	N/A	DE/CA09/0170/A10/IVD/007-01
P121-1111	Promotor™ Whole Blood Genomic DNA Extraction Kit		15 90 40 01	Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus	"Other"	N/A	DE/CA09/0170/A10/IVD/007-01
P111-1011	Promotor™ NES-32 Nucleic Acid Extraction System		26 02 10 01	NA Extraction Hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/006-01
P131-1481	Promotor™ HPV Human Papillomavirus Genotyping PCR-RDB Test Kit		15 04 80 03	Human Papilloma Virus	"Other"	N/A	DE/CA09/0170/A10/IVD/005-01
P131-1121	Promotor™ PCR-Fluorescence Detection Kit for Human Papillomavirus Genotype 16/18 DNA		15 04 80 03	Human Papilloma Virus	"Other"	N/A	DE/CA09/0170/A10/IVD/005-01

**Annex A dated Oct 17, 2017**  
**ACON Laboratories, Inc.**

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
P131-1301	Promotor™ TB Mycobacterium Tuberculosis PCR Test Kit		15 01 07 03	Mycobacteria Antibody Assays	"Other"	N/A	DE/CA09/0170/A10/IVD/004-01
G136-111	On Call® A1c HbA1c Test Kit		11 70 01 07	Glycosylated/Glycated Haemoglobin Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/003
G126-121	On Call® A1c HbA1c Control Solution		11 50 02 05	Diabetes Controls	"Other"	N/A	DE/CA09/0170/A10/IVD/002
L031-10411	ACON Syphilis Rapid Test Strip (Serum/Plasma)		15 70 01 05 00	Syphilis - Rapid Test	"Other"	N/A	DE/CA09/0170/A10/IVD/071-02
L031-10421	ACON Syphilis Rapid Test Strip (Serum/Plasma/Whole Blood)		15 70 01 05 00	Syphilis - Rapid Test	"Other"	N/A	DE/CA09/0170/A10/IVD/071-02
L031-10431	ACON Syphilis Rapid Test Cassette (Serum/Plasma)		15 70 01 05 00	Syphilis - Rapid Test	"Other"	N/A	DE/CA09/0170/A10/IVD/071-02
L031-10441	ACON Syphilis Rapid Test Cassette (Serum/Plasma/Whole Blood)		15 70 01 05 00	Syphilis - Rapid Test	"Other"	N/A	DE/CA09/0170/A10/IVD/071-02



**Annex A dated Oct 17, 2017  
ACON Laboratories, Inc.**

REF	Notified Device Names	optional information (not notified)	EDMA Code	EDMA Description	Class.	EC Certificate No. & Expiry Date	German Registration Number
L031-20111; L031-20171	ACON hCG Pregnancy Rapid Test Strip (Urine)		12 70 05 02	hCG Rapid Test	"Other"	N/A	DE/CA09/0170/A10/IVD/073
L031-20121; L031-20181	ACON hCG Pregnancy Rapid Test Strip (Urine/Serum)		12 70 05 02	hCG Rapid Test	"Other"	N/A	DE/CA09/0170/A10/IVD/073
L031-20141	ACON hCG Pregnancy Rapid Test Cassette (Urine/Serum)		12 70 05 02	hCG Rapid Test	"Other"	N/A	DE/CA09/0170/A10/IVD/073
L031-20152	BeSure hCG Pregnancy Rapid Test Cassette (Urine)		12 70 05 02	hCG Rapid Test	"Other"	N/A	DE/CA09/0170/A10/IVD/073
L031-20152	BeSure hCG Pregnancy Rapid Test Cassette (Urine)		12 70 05 02	hCG Rapid Test	Self-Testing	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/072-02
C111-6011	Mission Ultra Hemoglobin Testing System	(CCM-141)	23 07 10 00	RT_HHC Hardware + dedicated accessories or software	Self-Testing	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/074-01
C131-6011	Mission® Ultra Hemoglobin Test Strips	(CCS-141)	13 01 70 01 00	Haemoglobin (Hb)	Self-Testing	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/075-01
C121-6011	Mission® Ultra Hemoglobin Control Solution		13 01 50 04 00	Haemoglobin Control	Self-Testing	0123/V1 17 08 80997 017 - 12.09.2022	DE/CA09/0170/A10/IVD/076-01
C131-1021	Mission® AST Aspartate Aminotransferase Test Strips		11 01 01 10	Aspartate Amino-Transferase	"Other"	N/A	DE/CA09/0170/A10/IVD/077