



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.
5850 Oberlin Drive, #340
San Diego, CA 92121
USA

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 2020-10-26

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.

2020-10-26

Dr. Philipp Hohenbrink
Senior Consultant
MDSS GmbH

Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional Information/Categ ory Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
C131-1011	Mission® ALT Alanine Aminotransferase Test Strips		11 01 01 03	Alanine Amino-Transferase	"Other"	N/A	DE/CA09/0170/A10/IVD/022-01
C131-1021	Mission® AST Aspartate Aminotransferase Test Strips		11 01 01 10	Aspartate Amino-Transferase	"Other"	N/A	DE/CA09/0170/A10/IVD/077-01
G134-100, G134-11D	On Call® Blood Uric Acid Test Strip	(OGS-201)	11 02 01 32	Uric Acid	Self-Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/082-01
G134-100, G134-11D	On Call® Blood Uric Acid Test Strip	(OGS-201)	11 02 01 32	Uric Acid	"Other"	N/A	DE/CA09/0170/A10/IVD/087-01
G126-121	On Call® A1c HbA1c Control Solution		11 50 02 05	Diabetes Controls	"Other"	N/A	DE/CA09/0170/A10/IVD/002-01
G124-12D	On Call® Uric Acid Control Solution		11 50 02 05	Diabetes Controls	"Other"	N/A	DE/CA09/0170/A10/IVD/088-01
G124-12D	On Call® Uric Acid Control Solution		11 50 02 05	Diabetes Controls	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/080-01
U021-011, U021-021, U021-031	Mission® Liquid Urine Control		11 50 02 06	Urine Control	"Other"	N/A	DE/CA09/0170/A10/IVD/035-02
U021-015, U021-025, U021-035	Insight® Liquid Urine Control		11 50 02 06	Urine Control	"Other"	N/A	DE/CA09/0170/A10/IVD/035-02
U021-071, U021-081, U021-091	Mission® Liquid Dip tube Urine Control		11 50 02 06	Urine Control	"Other"	N/A	DE/CA09/0170/A10/IVD/035-02
U021-075, U021-085, U021-095	Insight® Liquid Dip tube Urine Control		11 50 02 06	Urine Control	"Other"	N/A	DE/CA09/0170/A10/IVD/035-02
U021-041, U021-051, U021-061	Mission® Dry Strip Urine Control		11 50 02 06	Urine Control	"Other"	N/A	DE/CA09/0170/A10/IVD/035-02
U021-045, U021-055, U021-065	Insight® Dry Strip Urine Control		11 50 02 06	Urine Control	"Other"	N/A	DE/CA09/0170/A10/IVD/035-02
C121-1051	Mission® ALT Control Solution		11 50 02 90	Other Specific Control (CC)	"Other"	N/A	DE/CA09/0170/A10/IVD/016-02
G134-106, G134-116	On Call® Chosen Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/025-07
G135-102, G135-112	On Call® Vivid Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/025-07
G135-109, G135-119	D-ONE Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/025-07
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 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/025-07
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 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/025-07

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Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional Information/Categ ory Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
G135-10H, G135-11H	On Call Extra Blood Glucose Test Strips	(OGS-191)	11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/025-07
G135-10U, G135-11U	On Call® Sure Blood Glucose Test Strip	(OGS-211)	11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/025-07
24118, 24119, 24120	GIMA Blood Glucose Test Strips	(OGS-211)	11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/025-07
G134-906A	Go-Keto Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/025-07
G133-11x	On Call® Plus Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/059-05
G134-101, G 134-111	On Call® Advanced Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/059-05
G134-102, G134-112	On Call® Platinum Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/059-05
G133-10D, G133-11D	On Call® Redi II Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/059-05
G135-10H, G135-11H	On Call® Extra Blood Glucose Test Strips	(OGS-191)	11 70 01 01	Glucose Test Strips	"other"	N/A	DE/CA09/0170/A10/IVD/086-03
G135-10U, G135-11U	On Call® Sure Blood Glucose Test Strip	(OGS-211)	11 70 01 01	Glucose Test Strips	"other"	N/A	DE/CA09/0170/A10/IVD/086-03
24118, 24119, 24120	GIMA Blood Glucose Test Strips	(OGS-211)	11 70 01 01	Glucose Test Strips	"other"	N/A	DE/CA09/0170/A10/IVD/086-03
G134-101, G134-111	On Call® Advanced Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	"other"	N/A	DE/CA09/0170/A10/IVD/086-03
G134-106, G134-116	On Call® Chosen Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	"other"	N/A	DE/CA09/0170/A10/IVD/086-03
G134-906A	Go-Keto Blood Glucose Test Strips		11 70 01 01	Glucose Test Strips	"other"	N/A	DE/CA09/0170/A10/IVD/086-03

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Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional Information/Categ ory Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	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/018-04
C131-2011; C131-2061	Mission® Cholesterol CHOL Total Cholesterol Test Device	(CCS-111)	11 70 01 02	Cholesterol Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/018-04
C131-2013	LipidScan Lipid Profile Test Device Total Cholesterol	(CCS-111)	11 70 01 02	Cholesterol Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/018-04
C131-2011; C131-2061	Mission® Cholesterol CHOL Total Cholesterol Test Device	(CCS-111)	11 70 01 02	Cholesterol Test Strips	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/069-07
C131-5011	Mission® Ultra-CHOL Total Cholesterol Test Strips	(CCS-101)	11 70 01 02	Cholesterol Test Strips	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/069-07
C131-2013	LipidScan Lipid Profile Test Device Total Cholesterol	(CCS-111)	11 70 01 02	Cholesterol Test Strips	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/069-07
C131-2031; C131-2081	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/012-02
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/012-02
C131-2031; C131-2081	Mission® Cholesterol HDL High Density Lipoprotein Test Device	(CCS-113)	11 70 01 03	HDL Test Strips	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/067-05
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 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/067-05
C131-2021; C131-2071	Mission® Cholesterol TRIG Triglyceride Test Device	(CCS-112)	11 70 01 05	Triglyceride Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/013-02
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/013-02
C131-2023	LipidScan Lipid Profile Test Device Triglycerides (TRIG)	(CCS-112)	11 70 01 05	Triglyceride Test Strips	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/068-05
C131-2021; C131-2071	Mission® Cholesterol TRIG Triglyceride Test Device	(CCS-112)	11 70 01 05	Triglyceride Test Strips	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/068-05

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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/003-02
G136-112	On Call® MultiPro HbA1c Test Kit	OCS-221	11 70 01 07	Glycosylated/Glycated Haemoglobin Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/003-02
GK134-10A, GK134-11A	On Call® Blood Ketone Test Strips		11 70 01 08	Ketone Test Strips (β-Hydroxybutyrate Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/098
GK134-90AA	Go-Keto Blood Ketone Test Strips		11 70 01 08	Ketone Test Strips (β-Hydroxybutyrate Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/098
GK134-10A, GK134-11A	On Call® Blood Ketone Test Strips		11 70 01 08	Ketone Test Strips (β-Hydroxybutyrate Test Strips)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/008-05
GK134-90AA	Go-Keto Blood Ketone Test Strips		11 70 01 08	Ketone Test Strips (β-Hydroxybutyrate Test Strips)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/008-05
C131-2041; C131-2051	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/011-02
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/011-02
C131-2041; C131-2051	Mission® Cholesterol 3-in-1 Lipid Panel Test Device	(CCS-114)	11 70 01 30	Multiple parameter blood test	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/066-05
C131-2043	LipidScan Lipid Profile Test Device Combo Lipid Profile	(CCS-114)	11 70 01 30	Multiple parameter blood test	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/066-05
C121-5011	Mission® Ultra Cholesterol Control Solution		11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06
C121-2011	Mission® Cholesterol Control Solution		11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06
C121-2023	LipidScan Lipid Profile Control Device		11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06
C121-2021	Mission® Cholesterol CTRL Control Device		11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06
G125-12H	On Call® Extra Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06
G125-12U	On Call® Sure Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06
24121	GIMA Glucose Control Solution	(OGC-211)	11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06
G126-122	On Call® MultiPro HbA1c Individual Controls	OGC-221	11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06
G124-121	On Call® Advanced Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06
G124-126	On Call® Chosen Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06

Annex A: 2020-10-26
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REF	Device Names (notified)	Optional Information/Categ ory Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
G124-12A	On Call® Ketone Control Solution		11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06
GK124-92AA	Go-Keto Ketone Control Solution		11 70 01 50	Controls (Blood Test Strips)	"Other"	N/A	DE/CA09/0170/A10/IVD/017-06
G124-126	On Call® Chosen Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/024-08
G125-122	On Call® Vivid Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/024-08
G125-129	D-ONE Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/024-08
G125-125	On Call® Sharp Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/024-08
G123-12C	On Call® Plus II Blood Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/024-08
G125-12H	On Call® Extra Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/024-08
G125-12U	On Call® Sure Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/024-08
24121	GIMA Glucose Control Solution	(OGC-211)	11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/024-08
G124-121	On Call® Advanced Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/058-06
G124-122	On Call® Platinum Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/058-06
G123-311	On Call® Plus Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/058-06
G123-371	On Call® Redi Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/058-06
G123-12D	On Call® Redi II Glucose Control Solution		11 70 01 50	Controls (Blood Test Strips)	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/058-06
C121-5011	Mission® Ultra Cholesterol Control Solution		11 70 01 50	Controls (Blood Test Strips)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/065-06
C121-2011	Mission® Cholesterol Control Solution		11 70 01 50	Controls (Blood Test Strips)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/065-06
C121-2023	LipidScan Lipid Profile Control Device		11 70 01 50	Controls (Blood Test Strips)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/065-06
C121-2021	Mission® Cholesterol CTRL Control Device		11 70 01 50	Controls (Blood Test Strips)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/065-06



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G124-12A	On Call® Ketone Control Solution		11 70 01 50	Controls (Blood Test Strips)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/065-06
GK124-92AA	Go-Keto Ketone Control Solution		11 70 01 50	Controls (Blood Test Strips)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/065-06
U031-XX1	Mission® Urinalysis Reagent Strips		11 70 02 01	Urine Single Test Strips (incl. Tablets)	"Other"	N/A	DE/CA09/0170/A10/IVD/031-02
U031-XX5	Insight® Urinalysis Reagent Strips		11 70 02 01	Urine Single Test Strips (incl. Tablets)	"Other"	N/A	DE/CA09/0170/A10/IVD/031-02
U033-XX1, U034-XX1	Mission® Expert Urinalysis Reagent Strips		11 70 02 01	Urine Single Test Strips (incl. Tablets)	"Other"	N/A	DE/CA09/0170/A10/IVD/031-02
U033-XX5, U034-XX5	Insight® Expert Urinalysis Reagent Strips		11 70 02 01	Urine Single Test Strips (incl. Tablets)	"Other"	N/A	DE/CA09/0170/A10/IVD/031-02
U031-XX1	Mission® Urinalysis Reagent Strips		11 70 02 01	Urine Single Test Strips (incl. Tablets)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/047-05
U031-XX5	Insight® Urinalysis Reagent Strips		11 70 02 01	Urine Single Test Strips (incl. Tablets)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/047-05
49110000xx	Blaas Check Urineweginfectie Thuisstest		11 70 02 01	Urine Single Test Strips (incl. Tablets)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/047-05
49110000xxx	Totaal Check Thuisstest Voor urine		11 70 02 01	Urine Single Test Strips (incl. Tablets)	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/047-05
U031-XX1	Mission® Urinalysis Reagent Strips		11 70 02 02 00	Urine Multi-constituent Test Strips	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/048-06
U031-XX5	Insight® Urinalysis Reagent Strips		11 70 02 02 00	Urine Multi-constituent Test Strips	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/048-06
49110000xx	Blaas Check Urineweginfectie Thuisstest		11 70 02 02 00	Urine Multi-constituent Test Strips	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/048-06
49110000xxx	Totaal Check Thuisstest Voor urine		11 70 02 02 00	Urine Multi-constituent Test Strips	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/048-06
U031-XX1	Mission® Urinalysis Reagent Strips		11 70 02 02 00	Urine Multi-constituent Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/057-02
U031-XX5	Insight® Urinalysis Reagent Strips		11 70 02 02 00	Urine Multi-constituent Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/057-02
U031-XX3 U033-XX1, U034-XX1	MITest Urinary Urinalysis Reagent Strips		11 70 02 02 00	Urine Multi-constituent Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/057-02
U033-XX5, U034-XX5	Mission® Expert Urinalysis Reagent Strips		11 70 02 02 00	Urine Multi-constituent Test Strips	"Other"	N/A	DE/CA09/0170/A10/IVD/057-02
I031-1011 I231-2021 I231-2022	Insight® Expert Urinalysis Reagent Strips Foresight® Allergen Test Kit Foresight® CEA EIA Kit Incontrol® CEA EIA Kit		11 70 02 02 00 12 02 01 06 12 03 01 31 12 03 01 31	Urine Multi-constituent Test Strips Immunoglobulin E - Screen Carcinoembryonic Antigen Carcinoembryonic Antigen	"Other" "Other" "Other"	N/A N/A N/A	DE/CA09/0170/A10/IVD/057-02 DE/CA09/0170/A10/IVD/009-02 DE/CA09/0170/A10/IVD/043-03 DE/CA09/0170/A10/IVD/043-03
I231-2031	Foresight® Total PSA EIA Test Kit		12 03 01 32	Total Prostatic Specific Antigen	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/015-06
I231-2032	Incontrol® Total PSA EIA Test Kit		12 03 01 32	Total Prostatic Specific Antigen	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/015-06
I231-2011	Foresight® AFP EIA Kit		12 03 90 01	Alphafetoprotein	"Other"	N/A	DE/CA09/0170/A10/IVD/061-03
I231-2012	Incontrol® AFP EIA Kit		12 03 90 01	Alphafetoprotein	"Other"	N/A	DE/CA09/0170/A10/IVD/061-03

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REF	Device Names (notified)	Optional Information/Categ ory Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
I231-3051	Foresight® Free T3 EIA Test Kit		12 04 01 01	Free Triiodothyronine	"Other"	N/A	DE/CA09/0170/A10/IVD/029-04
I231-3052	Incontrol® Free T3 EIA Test Kit		12 04 01 01	Free Triiodothyronine	"Other"	N/A	DE/CA09/0170/A10/IVD/029-04
I231-4051	Foresight® Free T3 CLIA Test Kit		12 04 01 01	Free Triiodothyronine	"Other"	N/A	DE/CA09/0170/A10/IVD/029-04
I231-3031	Foresight® Free T4 EIA Test Kit		12 04 01 02	Free Thyroxine	"Other"	N/A	DE/CA09/0170/A10/IVD/028-04
I231-3032	Incontrol® Free T4 EIA Test Kit		12 04 01 02	Free Thyroxine	"Other"	N/A	DE/CA09/0170/A10/IVD/028-04
I231-4031	Foresight® Free T4 CLIA Test Kit		12 04 01 02	Free Thyroxine	"Other"	N/A	DE/CA09/0170/A10/IVD/028-04
I231-3041	Foresight® Total T3 EIA Test Kit		12 04 01 05	Triiodothyronine	"Other"	N/A	DE/CA09/0170/A10/IVD/027-04
I231-3042	Incontrol® Total T3 EIA Test Kit		12 04 01 05	Triiodothyronine	"Other"	N/A	DE/CA09/0170/A10/IVD/027-04
I231-4041	Foresight® Total T3 CLIA Test Kit		12 04 01 05	Triiodothyronine	"Other"	N/A	DE/CA09/0170/A10/IVD/027-04
I231-3021	Foresight® Total T4 EIA Test Kit		12 04 01 07	Thyroxine	"Other"	N/A	DE/CA09/0170/A10/IVD/030-04
I231-3022	Incontrol® Total T4 EIA Test Kit		12 04 01 07	Thyroxine	"Other"	N/A	DE/CA09/0170/A10/IVD/030-04
I231-4021	Foresight® Total T4 CLIA Test Kit		12 04 01 07	Thyroxine	"Other"	N/A	DE/CA09/0170/A10/IVD/030-04
I231-3011	Foresight® TSH EIA Kit		12 04 01 11	Thyroid Stimulating Hormone	"Other"	N/A	DE/CA09/0170/A10/IVD/045-04
I231-3012	Incontrol® TSH EIA Kit		12 04 01 11	Thyroid Stimulating Hormone	"Other"	N/A	DE/CA09/0170/A10/IVD/045-04
I231-4011	Foresight® TSH CLIA Test Kit		12 04 01 11	Thyroid Stimulating Hormone	"Other"	N/A	DE/CA09/0170/A10/IVD/045-04
I231-4031	Foresight® FSH EIA Test Kit		12 05 01 04	Follicle Stimulating Hormone	"Other"	N/A	DE/CA09/0170/A10/IVD/014-02
I231-4032	Incontrol® FSH EIA Test Kit		12 05 01 04	Follicle Stimulating Hormone	"Other"	N/A	DE/CA09/0170/A10/IVD/014-02
I231-4021	Foresight® LH EIA Test Kit		12 05 01 05	Luteinising Hormone	"Other"	N/A	DE/CA09/0170/A10/IVD/021-02
I231-4022	Incontrol® LH EIA Test Kit		12 05 01 05	Luteinising Hormone	"Other"	N/A	DE/CA09/0170/A10/IVD/021-02
I231-4041	Foresight® PRL EIA Test Kit		12 05 01 08	Prolactin	"Other"	N/A	DE/CA09/0170/A10/IVD/020-02
I231-4042	Incontrol® PRL EIA Test Kit		12 05 01 08	Prolactin	"Other"	N/A	DE/CA09/0170/A10/IVD/020-02
I231-4011	Foresight® Rapid HCG EIA Test Kit		12 05 02 05	Human Chorionic Gonadotropin Total	"Other"	N/A	DE/CA09/0170/A10/IVD/019-03
I231-4012	Incontrol® Rapid HCG EIA Test Kit		12 05 02 05	Human Chorionic Gonadotropin Total	"Other"	N/A	DE/CA09/0170/A10/IVD/019-03
I231-4051	Foresight® HCG EIA Test Kit	(quantitative)	12 05 02 05	Human Chorionic Gonadotropin Total	"Other"	N/A	DE/CA09/0170/A10/IVD/019-03
I231-4052	Incontrol® HCG EIA Test Kit	(quantitative)	12 05 02 05	Human Chorionic Gonadotropin Total	"Other"	N/A	DE/CA09/0170/A10/IVD/019-03
C031-021	Mission® Saliva Alcohol Test Strip		12 09 02 07	Ethanol (Alcohol)	"Other"	N/A	DE/CA09/0170/A10/IVD/056-02
C031-025	Insight® Saliva Alcohol Test Strip		12 09 02 07	Ethanol (Alcohol)	"Other"	N/A	DE/CA09/0170/A10/IVD/056-02
C031-011,	Mission® Breath Alcohol Detector		12 09 02 07	Ethanol (Alcohol)	"Other"	N/A	DE/CA09/0170/A10/IVD/056-02
C031-031,	Insight® Breath Alcohol Detector		12 09 02 07	Ethanol (Alcohol)	"Other"	N/A	DE/CA09/0170/A10/IVD/056-02
C031-015,	Insight® Breath Alcohol Detector		12 09 02 07	Ethanol (Alcohol)	"Other"	N/A	DE/CA09/0170/A10/IVD/056-02
C031-035	Insight® Breath Alcohol Detector		12 09 02 07	Ethanol (Alcohol)	"Other"	N/A	DE/CA09/0170/A10/IVD/056-02
I031-30121	ACON Fecal Occult Blood Rapid Test Cassette (Feces)		12 70 03 21	Fecal Occult Blood - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/090-01
I031-30111	ACON Fecal Occult Blood Rapid Test Strips (Feces)		12 70 03 21	Fecal Occult Blood - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/090-01
I031-20242	Distinct Ovulation Rapid Test Midstream		12 70 05 04	LH - RT & POC	Self-Testing	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/083-01
I031-20232	Distinct LH Ovulation Rapid Test Cassette (Urine)		12 70 05 04	LH - RT & POC	Self-Testing	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/083-01

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L031-20211	ACON LH Ovulation Rapid Test Strip (Urine)		12 70 05 04	LH - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/089-01
L031-20221	ACON LH Ovulation Rapid Test Cassette (Urine)		12 70 05 04	LH - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/089-01
L031-20312	Distinct Ovulation & Pregnancy Rapid Test Midstream Combo Pack		12 70 05 90	Other Fertility/Pregnancy RT & POC	Self-Testing	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/081-01
L031-20152	Distinct Pregnancy Rapid Test Cassette (Urine)		12-70-05-02	HCG - RT & POC	Self-Testing	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/072-06
L031-20162	Distinct Pregnancy Rapid Test Midstream		12-70-05-02	HCG - RT & POC	Self-Testing	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/072-06
L031-20111, L031-20171	ACON hCG Pregnancy Rapid Test Strip (Urine)		12-70-05-02	HCG - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/073-02
L031-20121, L031-20181	ACON hCG Pregnancy Rapid Test Strip (Urine/Serum)		12-70-05-02	HCG - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/073-02
L031-20141	ACON hCG Pregnancy Rapid Test Cassette (Urine/Serum)		12-70-05-02	HCG - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/073-02
L031-20131	Acon hCG Pregnancy Rapid Test Cassette (Urine)		12-70-05-02	HCG - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/073-02
C121-9011	Mission® 3D Hematology Reagent (Cyto-Diluent)		13 01 01 01	CBC-Reagents (Cleaning-/Diluting-/Lysing-/Sheat- fluids)	"Other"	N/A	DE/CA09/0170/A10/IVD/078-01
C121-9021	Mission® 3D Hematology Reagent (Cyto-Lyser)		13 01 01 01	CBC-Reagents (Cleaning-/Diluting-/Lysing-/Sheat- fluids)	"Other"	N/A	DE/CA09/0170/A10/IVD/078-01
C121-9031	Mission® 3D Hematology Reagent (Mi-Po Cleaner)		13 01 01 01	CBC-Reagents (Cleaning-/Diluting-/Lysing-/Sheat- fluids)	"Other"	N/A	DE/CA09/0170/A10/IVD/078-01
C121-9041	Mission® 3D Hematology Control		13 01 50 03	Blood Multilevel Controls	"Other"	N/A	DE/CA09/0170/A10/IVD/092-01
C121-3031	Mission® Hb Hemoglobin Control Strip		13 01 50 04	Haemoglobin Control	"Other"	N/A	DE/CA09/0170/A10/IVD/032-04
C121-3035	Insight® Hb Hemoglobin Control Strip		13 01 50 04	Haemoglobin Control	"Other"	N/A	DE/CA09/0170/A10/IVD/032-04
C122-3011	Mission® Plus Hb Hemoglobin Control Strip	(Optic Check)	13 01 50 04	Haemoglobin Control	"Other"	N/A	DE/CA09/0170/A10/IVD/032-04
C122-3021	Mission® Plus Hb Hemoglobin Control Device	(Optic Check)	13 01 50 04	Haemoglobin Control	"Other"	N/A	DE/CA09/0170/A10/IVD/032-04
C121-3091	Mission® Hb Hemoglobin Control Solution		13 01 50 04	Haemoglobin Control	"Other"	N/A	DE/CA09/0170/A10/IVD/032-04
C121-6011	Mission® Ultra Hemoglobin Control Solution		13 01 50 04	Haemoglobin Control	"Other"	N/A	DE/CA09/0170/A10/IVD/032-04
C121-6011	Mission® Ultra Hemoglobin Control Solution		13 01 50 04	Haemoglobin Controls	Self-Testing	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/076-03
C131-6011	Mission Ultra Hemoglobin Test Strips	(CCS-141)	13 01 70 01	Haemoglobin (Hb)	Self-Testing	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/075-03

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REF	Device Names (notified)	Optional Information/Categ ory Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
C131-3011, C131-3021	Mission® Hb Hemoglobin Test Strips		13 01 70 01	Haemoglobin (Hb)	"Other"	N/A	DE/CA09/0170/A10/IVD/033-04
C131-3015	Insight® Hb Hemoglobin Test Strips		13 01 70 01	Haemoglobin (Hb)	"Other"	N/A	DE/CA09/0170/A10/IVD/033-04
C132-3011, C132-3031	Mission® Plus Hb Hemoglobin Test Strips		13 01 70 01	Haemoglobin (Hb)	"Other"	N/A	DE/CA09/0170/A10/IVD/033-04
C132-3021, C132-3041	Mission® Plus Hb Hemoglobin Test Devices		13 01 70 01	Haemoglobin (Hb)	"Other"	N/A	DE/CA09/0170/A10/IVD/033-04
C131-6011	Mission Ultra Hemoglobin Test Strips	(CCS-141)	13 01 70 01	Haemoglobin (Hb)	"Other"	N/A	DE/CA09/0170/A10/IVD/033-04
C131-4011	Mission® PT Coagulation Test Strips	(CCS-121)	13 02 70 01	Prothrombin Time RT & POC	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/063-05
C132-4011	Mission® PT/INR Test Strips	(CCS-151)	13 02 70 01	Prothrombin Time RT & POC	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/063-05
LMINR-0002; LMINR-0003	LUMIRATEK PT/INR Test Strips		13 02 70 01	Prothrombin Time RT & POC	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/063-05
C121-4011	Mission® PT Coagulation Control Solution		13 02 70 50	Haemostasis Controls - RT & POC	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/062-05
C122-4011	Mission® PT/INR Control Solution		13 02 70 50	Haemostasis Controls - RT & POC	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/062-05
LMINR-0004	LUMIRATEK PT/INR Control Solution		13 02 70 50	Haemostasis Controls - RT & POC	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/062-05
U031-021	Mission® UTI Urinary Tract Infection Test Strips		14 01 07 02	Urine Screening Manual - Strips, etc.	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/046-06
U031-025	Insight® UTI Urinary Tract Infection Test Strips		14 01 07 02	Urine Screening Manual - Strips, etc.	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/046-06
U031-023	ValMed UTI Urinary Tract Infection Test Strips		14 01 07 02	Urine Screening Manual - Strips, etc.	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/046-06
U031-02A	HealthyMe UTI Urinary Tract Infection Test Strips		15 01 07 02	Urine Screening Manual - Strips, etc.	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/046-06
I231-1042	Incontrol® Total Syphilis Antibody EIA Test Kit		15 01 03 03	Syphilis Antibody Assays Total	"Other"	N/A	DE/CA09/0170/A10/IVD/054-03
I231-1041	Foresight® Total Syphilis Antibody EIA Test Kit		15 01 03 03	Syphilis Antibody Assays Total	"Other"	N/A	DE/CA09/0170/A10/IVD/054-03
I231-1231	Foresight® H. pylori Antigen EIA Test Kit		15 01 04 01	H. Pylori Antigen Detection	"Other"	N/A	DE/CA09/0170/A10/IVD/055-03
I231-1232	Incontrol® H. pylori Antigen EIA Test Kit		15 01 04 01	H. Pylori Antigen Detection	"Other"	N/A	DE/CA09/0170/A10/IVD/055-03
I231-1241	Foresight® H. pylori IgG EIA Test Kit		15 01 04 03	H. Pylori Antibody Assays	"Other"	N/A	DE/CA09/0170/A10/IVD/042-04
I231-1242	Incontrol® H. pylori IgG EIA Test Kit		15 01 04 03	H. Pylori Antibody Assays	"Other"	N/A	DE/CA09/0170/A10/IVD/042-04

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I031-10611	H. pylori Antibody Rapid Test Cassette (Serum/Plasma)		15 01 04 03	H. Pylori Antibody Assays	"Other"	N/A	DE/CA09/0170/A10/IVD/042-04
I031-10621	H. pylori Antibody Rapid Test Cassette (Serum/Plasma/Whole Blood)		15 01 04 03	H. Pylori Antibody Assays	"Other"	N/A	DE/CA09/0170/A10/IVD/042-04
P131-1301	Promotor™ TB Mycobacterium Tuberculosis PCR Test Kit		15 01 07 03	Mycobacteria Antibody Assays	"Other"	N/A	DE/CA09/0170/A10/IVD/004-02
I231-1211	Foresight® HEV IgM EIA Kit		15 02 05 06	HEV Antibody IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/044-03
I231-1212	Incontrol® HEV IgM EIA Kit		15 02 05 06	HEV Antibody IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/044-03
I231-1112	Incontrol® Rubella IgG EIA Test Kit		15 04 01 05	Rubella Virus IgG	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/038-06
I231-1111	Foresight® Rubella IgG EIA Test Kit		15 04 01 05	Rubella Virus IgG	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/038-06
I231-1121	Foresight® Rubella IgM EIA Test Kit		15 04 01 06	Rubella Virus IgM	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/039-06
I231-1122	Incontrol® Rubella IgM EIA Test Kit		15 04 01 06	Rubella Virus IgM	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/039-06
I231-1132	Incontrol® CMV IgG EIA Test Kit		15 04 02 05	CMV IgG	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/036-06
I231-1131	Foresight® CMV IgG EIA Test Kit		15 04 02 05	CMV IgG	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/036-06
I231-1141	Foresight® CMV IgM EIA Test Kit		15 04 02 06	CMV IgM	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/037-06
I231-1142	Incontrol® CMV IgM EIA Test Kit		15 04 02 06	CMV IgM	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/037-06
I231-1192	Incontrol® HSV 1/2 IgG EIA Test Kit		15 04 03 05	HSV 1+2 IgG	"Other"	N/A	DE/CA09/0170/A10/IVD/053-03
I231-1191	Foresight® HSV 1/2 IgG EIA Test Kit		15 04 03 05	HSV 1+2 IgG	"Other"	N/A	DE/CA09/0170/A10/IVD/053-03
I231-1202	Incontrol® HSV 1/2 IgM EIA Test Kit		15 04 03 06	HSV 1+2 IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/050-03
I231-1201	Foresight® HSV 1/2 IgM EIA Test Kit		15 04 03 06	HSV 1+2 IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/050-03
I231-1152	Incontrol® HSV 1 IgG EIA Test Kit		15 04 03 08	HSV 1 IgG	"Other"	N/A	DE/CA09/0170/A10/IVD/052-03
I231-1151	Foresight® HSV 1 IgG EIA Test Kit		15 04 03 08	HSV 1 IgG	"Other"	N/A	DE/CA09/0170/A10/IVD/052-03
I231-1162	Incontrol® HSV 1 IgM EIA Test Kit		15 04 03 09	HSV 1 IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/010-03
I231-1161	Foresight® HSV 1 IgM EIA Test Kit		15 04 03 09	HSV 1 IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/010-03
I231-1172	Incontrol® HSV 2 IgG EIA Test Kit		15 04 03 11	HSV 2 IgG	"Other"	N/A	DE/CA09/0170/A10/IVD/051-03
I231-1171	Foresight® HSV 2 IgG EIA Test Kit		15 04 03 11	HSV 2 IgG	"Other"	N/A	DE/CA09/0170/A10/IVD/051-03
I231-1182	Incontrol® HSV 2 IgM EIA Test Kit		15 04 03 12	HSV 2 IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/049-03
I231-1181	Foresight® HSV 2 IgM EIA Test Kit		15 04 03 12	HSV 2 IgM	"Other"	N/A	DE/CA09/0170/A10/IVD/049-03
P131-1121	Promotor™ PCR-Fluorescence Detection Kit for Human Papillomavirus Genotype 16/18 DNA		15 04 08 41	Partial Genotyping High-Risk HPV - NA reagents	"Other"	N/A	DE/CA09/0170/A10/IVD/093
P131-1481	Promotor™ HPV Human Papillomavirus Genotyping PCR-RDB Test Kit		15 04 08 42	Full Genotyping High-Risk + Low-Risk HPV - NA reagents	"Other"	N/A	DE/CA09/0170/A10/IVD/005-02
P131-1501	Promotor™ HPV 15 High-risk with 16/18 Genotyping PCR Test Kit		15 04 08 42	Full Genotyping High-Risk + Low-Risk HPV - NA reagents	"Other"	N/A	DE/CA09/0170/A10/IVD/005-02
P131-1591	Promotor™ SARS-CoV-2 RT-PCR Test Kit		15 04 40 19	Coronavirus - NA Reagents (PCR test)	"Other"	N/A	DE/CA09/0170/A10/IVD/097-01



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I231-1321	Foresight® SARS-CoV-2 IgG EIA Test Kit		15 04 80 19	Coronavirus	"Other"	N/A	DE/CA09/0170/A10/IVD/099
I231-1331	Foresight® SARS-CoV-2 IgM EIA Test Kit		15 04 80 19	Coronavirus	"Other"	N/A	DE/CA09/0170/A10/IVD/099
I231-1091	Foresight® Toxoplasma IgG EIA Test Kit		15 05 01 05	Toxoplasma Antibody IgG	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/040-06
I231-1092	Incontrol® Toxoplasma IgG EIA Test Kit		15 05 01 05	Toxoplasma Antibody IgG	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/040-06
I231-1101	Foresight® Toxoplasma IgM EIA Test Kit		15 05 01 06	Toxoplasma Antibody IgM	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/041-06
I231-1102	Incontrol® Toxoplasma IgM EIA Test Kit		15 05 01 06	Toxoplasma Antibody IgM	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/041-06
I031-10711	ACON H. pylori Antigen Rapid Test Cassette (Feces)		15 70 01 02	H. Pylori - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/085-02
I031-10411	ACON Syphilis Rapid Test Strip (Serum/Plasma)		15 70 01 05	Syphilis - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/071-02
I031-10421	ACON Syphilis Rapid Test Strip (Serum/Plasma/Whole Blood)		15 70 01 05	Syphilis - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/071-02
I031-10431	ACON Syphilis Rapid Test Cassette (Serum/Plasma)		15 70 01 05	Syphilis - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/071-02
I031-10441	ACON Syphilis Rapid Test Cassette (Serum/Plasma/Whole Blood)		15 70 01 05	Syphilis - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/071-02
I031-11011	Malaria P.f/P.v Antigen Rapid Test Cassette (Whole Blood)		15 70 05 01	Plasmodium (Malaria) - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/091-01
I031-10911	Malaria P.f/Pan Antigen Rapid Test Cassette (Whole Blood)		15 70 05 01	Plasmodium (Malaria) - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/091-01
I031-11815	Flowflex® SARS-CoV-2 Antigen Rapid Test		15 70 90 08	Coronavirus – RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/100
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/007-03
P121-1121; P121-1221	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/007-03
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/007-03
P121-1301	Promotor® Nucleic Acid 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/007-03
P121-1051	Promotor Viral Nucleic Acid Isolation 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/007-03
P121-1291	Promotor Viral DNA/ RNA Isolation 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/007-03

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Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional Information/Categ ory Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
L031-11211	ACON® Dengue NS1 Antigen Rapid Test Cassette (Serum/Plasma/Whole Blood)		15 70 90 07	Dengue - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/094-01
L031-11311	ACON® Dengue IgG/IgM Rapid Test Cassette (Serum/Plasma/Whole Blood)		15 70 90 07	Dengue - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/094-01
L031-11511	ACON® Dengue NS1 Ag & IgG/IgM Combo Rapid Test Cassette (Serum/Plasma/Whole Blood)		15 70 90 07	Dengue - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/094-01
L031-11711	ACON® SARS-CoV-2 IgG/IgM Rapid Test		15 70 90 90	Other Other Virology - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/095
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/023-02
C121-1011	Mission® Optical Check Strips		21 01 10 01	CH Hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/023-02
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/023-02
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 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G115-102	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 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G115-112, G115-122, G115-132	On Call® Vivid Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G115-109	D-ONE Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
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 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
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 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
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 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
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 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G115-10H	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 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G115-11H, G115-12H, G115-13H	On Call® Extra Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07

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Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional Information/Categ ory Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
G115-10T	On Call® Extra Mobile Blood Glucose Monitoring System	(OGM-281)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G115-11T, G115-12T, G115-13T	On Call® Extra Mobile Blood Glucose Meter	(OGM-281)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
GU114-11D	On Call® GU Dual Blood Glucose & Uric Acid Meter	(OGM-201)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G115-10W	On Call® Sure Sync Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G115-11W, G115-12W, G115-13W	On Call® Sure Sync Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G115-10U	On Call® Sure Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G115-11U, G115-12U, G115-13U	On Call® Sure Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G117-107	On Call® Extra Voice Blood Glucose Monitoring System	(OGM-291)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G117-117, G117-127, G117-137	On Call® Extra Voice Blood Glucose Meter	(OGM-291)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
24110, 24111	GIMA Blood Glucose Monitoring System	(OGM-211)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
24114	GIMA Bluetooth® Blood Glucose Monitoring System	(OGM-212)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07

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REF	Device Names (notified)	Optional Information/Categ ory Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
24108	GIMA Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
GK114-908A	Go-Keto Blood & ketone Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/026-07
G113-111, G113-112, G113-211, G113-214, G113-215, G113-216, G114-101, G114-111, G114-121, G114-131	On Call® Plus Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/060-08
G113-171, G113-271, G113-274, G113-151, G113-251, G113-152, G113-251, G113-254, G114-102, G114-112, G114-122, G114-132	On Call® EZ II Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	Annex II - List B	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/060-08
G115-10T	On Call® Extra Mobile Blood Glucose Monitoring System	(OGM-281)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
G115-11T, G115-12T, G115-13T	On Call® Extra Mobile Blood Glucose Meter	(OGM-281)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
G115-11D	On Call® GU Dual Blood Glucose & Uric Acid Meter	(OGM-201)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
G115-10W, G115-11W, G115-12W, G115-13W	On Call® Sure Sync Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
G115-10U	On Call® Sure Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05

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Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional Information/Categ ory Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
G115-11U, G115-12U, G115-13U	On Call® Sure Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
G117-107	On Call® Extra Voice Blood Glucose Monitoring System	(OGM-291)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
G117-117, G117-127, G117-137	On Call® Extra Voice Blood Glucose Meter	(OGM-291)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
24110, 24111	GIMA Blood Glucose Monitoring System	(OGM-211)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
24114	GIMA Bluetooth® Blood Glucose Monitoring System	(OGM-212)	21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
24108	GIMA Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
GK114-138	On Call® GK Dual Blood Glucose & Ketone Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
GK114-90BA	Go-Keto Blood & Ketone Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
G115-10H	On Call® Extra Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
G115-11H, G115-12H, G115-13H	On Call® Extra Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
G115-102	On Call® Vivid Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
G115-112, G115-122, G115-132	On Call® Vivid Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05

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Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional Information/Categ ory Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
G113-111, G113-112	On Call® Plus Blood Glucose Monitoring System		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
G113-211, G113-214, G113-215, G113-216	On Call® Plus Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
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/001-07
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/001-07
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/001-07
U121-101	Mission® Printer Paper Rolls		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
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/001-07
U221-115	Insight® Barcode Reader		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
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/001-07
U121-105	Insight® Printer Paper Rolls		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
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/001-07
U223-111	Mission® Expert Barcode Reader		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07

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Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional Information/Categ ory Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
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/001-07
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/001-07
U223-115	Insight® Expert Barcode Reader		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
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/001-07
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/001-07
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/001-07
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/001-07
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/001-07
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/001-07
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/001-07

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Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional Information/Categ ory Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
U213-105, U213-115	Insight® Expert U500 Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
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/001-07
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/001-07
U124-111	Mission® Barcode Reader		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
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/001-07
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/001-07
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/001-07
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/001-07
5004001, 5004001BCR	Urispin U120 Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07

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Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional Information/Categ ory Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	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/001-07
5004002	Urispin U500 Urine Analyzer (SPINREACT)		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
U221-113	Urispin Urine Analyzer Barcode Reader		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
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/001-07
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/001-07
U121-103	Urispin Pinter Paper Rolls		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
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/001-07
C111-2011	Mission® Cholesterol Monitoring System	(CCM-111)	21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
C111-2021	Mission® Cholesterol Meter	(CCM-111)	21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07

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REF	Device Names (notified)	Optional Information/Categ ory Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
C111-2041	Mission® Cholesterol Meter	(CCM-111) 5 extra lancets	21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
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/001-07
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/001-07
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/001-07
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/001-07
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/001-07
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/001-07
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/001-07
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/001-07
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/001-07
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/001-07
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/001-07
U123-105	Insight® U120 Expert Paper Rolls		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
5004003	Urispin U120 Smart Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
U114-103	SURESIGN® U120 Ultra Urine Analyzer		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
5040007	Exacto® U120 Ultra		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
BU121-103	Exacto® Printer Paper Rolls (Thermal)		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07

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REF	Device Names (notified)	Optional Information/Categ ory Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
BU124-113	Exacto® BarCode Reader		21 07 10 03	RT_CC hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/001-07
C111-2011	Mission® Cholesterol Monitoring System	(CCM-111)	21 07 10 03	RT_CC Hardware + accessories + consumables + software	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/070-05
C111-2021	Mission® Cholesterol Meter	(CCM-111)	21 07 10 03	RT_CC Hardware + accessories + consumables + software	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/070-05
C111-2041	Mission® Cholesterol Meter	(CCM-111) 5 extra lancets	21 07 10 03	RT_CC Hardware + accessories + consumables + software	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/070-05
C111-5011	Mission® Ultra Cholesterol Monitoring System	(CCM-101)	21 07 10 03	RT_CC Hardware + accessories + consumables + software	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/070-05
C111-2023	LipidScan Lipid Profile Analyzer	(CCM-111)	21 07 10 03	RT_CC Hardware + accessories + consumables + software	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/070-05
G116-112, G116-122	On Call® MultiPro Analyzer	OGM-221	21 07 10 09	RT_CI Hardware + dedicated accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/096
C111-9011	Mission® HA-360 3-Diff Automatic Hematology Analyzer		23 01 10 01	CC Hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/A10/IVD/079-01
C111-3021, C111-3031	Mission® Hb Hemoglobin Testing System		23 07 10 00	RT_HHC Hardware + dedicated accessories or software	"Other"	N/A	DE/CA09/0170/A10/IVD/034-04
C111-3015, C111-3025, C111-3035	Insight® Hb Hemoglobin Testing System		23 07 10 00	RT_HHC Hardware + dedicated accessories or software	"Other"	N/A	DE/CA09/0170/A10/IVD/034-04
C112-3011, C112-3021, C112-3031	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/034-04
C121-3021	Mission® Hb Data Transfer Kit		23 07 10 00	RT_HHC Hardware + dedicated accessories or software	"Other"	N/A	DE/CA09/0170/A10/IVD/034-04
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/034-04
C111-6011	Mission Ultra Hemoglobin Testing System	(CCM-141)	23 07 10 00	RT_HHC Hardware + dedicated accessories or software	Self-Testing	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/074-03
C111-4011	Mission® PT Coagulation Monitoring System	(CCM-121)	23 07 10 02	RT_Coagulation Hardware + accessories + consumables + software	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/064-05
C112-4021	Mission® PT/INR Monitoring System	(model CCM-151)	23 07 10 02	RT_Coagulation Hardware + accessories + consumables + software	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/064-05
LMNR-0001	LUMIRATEK PT/INR Monitoring System		23 07 10 02	RT_Coagulation Hardware + accessories + consumables + software	Self Test	0123/V1 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/064-05
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/006-02

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REF	Device Names (notified)	Optional Information/Categ ory Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
G123-191	Testamed Diabetes Care Lancets	10	UMDNS 10-440	Lancets, Blood	Ila	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
C121-3041	Mission® Lancets	10	UMDNS 10-440	Lancets, Blood	Ila	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
G123-191	Testamed Diabetes Care Soft Lancets	10	UMDNS 10-440	Lancets, Blood	Ila	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
G123-781 C121-3061	On Call Safety Lancets I	10	UMDNS 10-440	Lancets, Blood	Ila	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
C121-3061	Mission® Safety Lancets I	10	UMDNS 10-440	Lancets, Blood	Ila	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
N/A (kit component)	D-One Lancets	10	UMDNS 10-440	Lancets, Blood	Ila	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
G124-10A	On Call Lancets	10	UMDNS 10-440	Lancets, Blood	Ila	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
G123-191	Testamed Diabetes Care Lancets	10	UMDNS 10-440	Lancets, Blood	Ila	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
G123-191	Testamed Diabetes Care Soft Lancets	10	UMDNS 10-440	Lancets, Blood	Ila	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
G123-782	On Call® Safety Lancets III	10	UMDNS 10-440	Lancets, Blood	Ila	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
C121-3101	Mission® Safety Lancets III	10	UMDNS 10-440	Lancets, Blood	Ila	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
G124-90AA	Swiss Point of Care Lancets	10	UMDNS 10-440	Lancets, Blood	Ila	0123/G1 104507 0002 exp. 2023-09-06	DE/CA09/0170/A10/003-05
C121-3081	Mission® Capillary Transfer Tubes	10	UMDNS 15-192	Tube, Capillary	I	N/A	DE/CA09/0170/A10/001-02
C121-3085	Insight® Capillary Transfer Tubes	10	UMDNS 15-192	Tube, Capillary	I	N/A	DE/CA09/0170/A10/001-02
G123-291	Testamed Diabetes Care Lancing Device	10	UMDNS 16-380	Lancing Devices, Blood	I	N/A	DE/CA09/0170/A10/002-03
C121-3051	Mission® Lancing Device	10	UMDNS 16-380	Lancing Devices, Blood	I	N/A	DE/CA09/0170/A10/002-03
N/A (kit component)	D-One Lancing Device	10	UMDNS 16-380	Lancing Devices, Blood	I	N/A	DE/CA09/0170/A10/002-03
G124-11A	On Call Lancing Device	10	UMDNS 16-380	Lancing Devices, Blood	I	N/A	DE/CA09/0170/A10/002-03
G124-17A	On Call GenTouch Lancing Device	10	UMDNS 16-380	Lancing Devices, Blood	I	N/A	DE/CA09/0170/A10/002-03
G124-91AA	Swiss Point of Care Lancing Device	10	UMDNS 16-380	Lancing Devices, Blood	I	N/A	DE/CA09/0170/A10/002-03