

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

REF	Device Names (notified)	Optional information/Catagory 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
G134-10D, 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
G134-10D, 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 Diptube 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 Diptube 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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REF	Device Names (notified)	Optional information/Category 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, G134-111	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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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	OGS-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	GIIMA 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



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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
4911000xxx	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
4911000xxx	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	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-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/057-02
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/057-02
I031-1011	Foresight® Allergen Test Kit		12 02 01 06	Immunoglobulin E - Screen	"Other"	N/A	DE/CA09/0170/A10/IVD/009-02
I231-2021	Foresight® CEA EIA Kit		12 03 01 31	Carcinoembryonic Antigen	"Other"	N/A	DE/CA09/0170/A10/IVD/043-03
I231-2022	Incontrol® CEA EIA Kit		12 03 01 31	Carcinoembryonic Antigen	"Other"	N/A	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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Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional information/Catagory 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
I331-4051	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
I331-4031	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
I331-4041	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
I331-4021	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
I331-4011	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, C031-031	Mission® Breath Alcohol Detector		12 09 02 07	Ethanol (Alcohol)	"Other"	N/A	DE/CA09/0170/A10/IVD/056-02
C031-015, C031-035	Insight® Breath Alcohol Detector		12 09 02 07	Ethanol (Alcohol)	"Other"	N/A	DE/CA09/0170/A10/IVD/056-02
L031-30121	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
L031-30111	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
L031-20242	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
L031-20232	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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Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional Information/Catagory Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
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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Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional information/Catagory 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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Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional information/Catagory Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
L031-10611	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
L031-10621	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 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 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

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

REF	Device Names (notified)	Optional information/Catagory Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
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
L031-10711	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
L031-10411	ACON Syphilis Rapid Test Strip (Serum/Plasma)		15 70 01 05	Syphilis - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/071-02
L031-10421	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
L031-10431	ACON Syphilis Rapid Test Cassette (Serum/Plasma)		15 70 01 05	Syphilis - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/071-02
L031-10441	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
L031-11011	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
L031-10911	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
L031-11815	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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Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional information/Catagory 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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Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional information/Catagory 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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Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional information/Catagory 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
GK114-90BA	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	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
G113-211, G113-214, G113-215, G113-216	On Call® Plus 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/060-08
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 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/060-08
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 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/060-08
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 104507 0003 exp. 2022-09-12	DE/CA09/0170/A10/IVD/060-08
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 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
GU114-11D	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	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
G115-11W, G115-12W, G115-13W	On Call® Sure Sync Blood Glucose Meter		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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Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional information/Categorical 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	GIIMA 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	GIIMA 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	GIIMA Blood Glucose Meter		21 07 10 01	RT_BGM Hardware + accessories + consumables + software	"other"	N/A	DE/CA09/0170/A10/IVD/084-05
GK114-13B	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



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

REF	Device Names (notified)	Optional information/Catagory 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

B



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

REF	Device Names (notified)	Optional information/Category Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
U123-131	Misson® 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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Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional Information/Catagory 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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Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional Information/Categorical 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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Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional Information/Catagory 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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Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional information/Catagory 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
LMINR-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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Annex A: 2020-10-26
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional Information/Catagory 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
G123-7B1 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
G123-7B2	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

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