

EG KONFORMITÄTSERKLÄRUNG

EC DECLARATION OF CONFORMITY

ORGENTEC Diagnostika GmbH

Carl-Zeiss-Straße 49-51, 55129 Mainz, GERMANY

Wir erklären in eigener Verantwortung, dass die unten gelisteten ORGENTEC IVD Produkte
We declare in our sole responsibility that ORGENTEC IVD product products listed below

zur quantitativen oder qualitativen in-vitro-Bestimmung bestimmt sind und entsprechend Art. 9 Abs. Satz 1 der Europäischen Richtlinie 98/79/EG als „Sonstige Produkte“ klassifiziert sind.

as intended for use in quantitative or qualitative in vitro determinations are classified as "Other Devices" according to article 9 paragraph 1 sentence 1 of the European directive 98/79/EC.

Die Produkte stimmen mit den Grundlegenden Anforderungen und allen zutreffenden Bestimmungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über in-vitro-Diagnostika überein. Die Konformität zur Richtlinie wurde durch ein Konformitätsbewertungsverfahren nach Anhang III der Richtlinie festgestellt.

These products conform with the essential requirements and meet the appropriate provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Conformity was proved by a conformity assessment procedure referred to in annex III of the directive.

Liste angewendeter Normen

List of standards applied for CE marking

EN ISO 9001, EN ISO 13485, EN ISO 14971, EN ISO 18113-2, EN ISO 15223 for reagents.

For electrical instruments also EN 591, EN 61010-2, EN 61010-2-081, EN 61326, EN 1658, EN 60812

Mainz, 11.05.2017

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 Dr. Christian Löbke
 (QMB / Quality Management Representative)

Diese Konformitätserklärung gilt ab 11.05.2017 bis 11.05.2019.

This declaration of conformity is valid from 2017-05-11 until 2019-05-11.

Notification pursuant to §25 Abs. 3 Nr. 3 Medical Devices Act, MPG

Code	IVD Name	Classification	Registration No	Date	EDMS code
ORG 502	Anti-TG	"other devices"	DE/CA33/9002/018	16.10.2002	12-10-03-04-00
ORG 503	Anti-TPO	"other devices"	DE/CA33/9002/019	16.10.2002	12-10-03-01-00
ORG 506	ENAscreen	"other devices"	DE/CA33/9002/020	16.10.2002	12-10-01-02-00
ORG 507	Anti-Histone	"other devices"	DE/CA33/9002/021	16.10.2002	12-10-01-07-00
ORG 508	Anti-SS-A	"other devices"	DE/CA33/9002/022	16.10.2002	12-10-01-12-00
ORG 509	Anti-SS-B	"other devices"	DE/CA33/9002/023	16.10.2002	12-10-01-13-00
ORG 510	Anti-Sm	"other devices"	DE/CA33/9002/024	16.10.2002	12-10-01-11-00
ORG 511	Anti-RNP/Sm	"other devices"	DE/CA33/9002/025	16.10.2002	12-10-01-14-00

ORG 512	Anti-Scl-70	"other devices"	DE/CA33/9002/026	16.10.2002	12-10-01-10-00
ORG 513	Anti-Jo-1	"other devices"	DE/CA33/9002/027	16.10.2002	12-10-01-08-00
ORG 514	ENACombi	"other devices"	DE/CA33/9002/028	16.10.2002	12-10-01-90-00
ORG 515	Anti-Cardiolipin IgG/IgM	"other devices"	DE/CA33/9002/029	16.10.2002	12-10-90-01-00
ORG 515A	Anti-Cardiolipin IgA	"other devices"	DE/CA33/9002/030	16.10.2002	12-10-90-01-00
ORG 515S	Anti-Cardiolipin Screen	"other devices"	DE/CA33/9002/031	16.10.2002	12-10-90-01-00
ORG 516	AMA-M2	"other devices"	DE/CA33/9002/032	16.10.2002	12-10-90-02-00
ORG 517	Anti-Rib-P	"other devices"	DE/CA33/9002/033	16.10.2002	12-10-90-20-00
ORG 518	Anti-PR3 (cANCA)	"other devices"	DE/CA33/9002/034	16.10.2002	12-10-90-10-00
ORG 519	Anti-MPO (pANCA)	"other devices"	DE/CA33/9002/035	16.10.2002	12-10-90-09-00
ORG 520	Anti-Insulin	"other devices"	DE/CA33/9002/036	16.10.2002	12-06-01-04-00
ORG 521	Anti-beta-2-Glycoprotein I IgG/IgM	"other devices"	DE/CA33/9002/037	16.10.2002	12-10-90-04-00
ORG 521A	Anti-beta-2-Glycoprotein I IgA	"other devices"	DE/CA33/9002/038	16.10.2002	12-10-90-04-00
ORG 521S	Anti-beta-2-Glycoprotein I Screen	"other devices"	DE/CA33/9002/039	16.10.2002	12-10-90-04-00
ORG 522A	Rheumatoid Factor IgA	"other devices"	DE/CA33/9002/040	16.10.2002	12-11-01-10-00
ORG 522G	Rheumatoid Factor IgG	"other devices"	DE/CA33/9002/041	16.10.2002	12-11-01-10-00
ORG 522M	Rheumatoid Factor IgM	"other devices"	DE/CA33/9002/042	16.10.2002	12-11-01-10-00
ORG 522S	Rheumatoid Factor Screen	"other devices"	DE/CA33/9002/043	16.10.2002	12-11-01-10-00
ORG 523	Anti-BPI	"other devices"	DE/CA33/9002/044	16.10.2002	12-10-90-90-00
ORG 524	Anti-Elastase	"other devices"	DE/CA33/9002/045	16.10.2002	12-10-90-90-00
ORG 525	Anti-Cathepsin G	"other devices"	DE/CA33/9002/046	16.10.2002	12-10-90-90-00
ORG 526	Anti-Lysozyme	"other devices"	DE/CA33/9002/047	16.10.2002	12-10-90-90-00
ORG 527	Anti-Lactoferrin	"other devices"	DE/CA33/9002/048	16.10.2002	12-10-90-90-00
ORG 528	Anti-Nucleosome	"other devices"	DE/CA33/9002/049	16.10.2002	12-10-90-18-00
ORG 529	Anti-Phospholipid Screen IgG/IgM	"other devices"	DE/CA33/9002/050	16.10.2002	12-10-90-90-00
ORG 530	ANCAcombi	"other devices"	DE/CA33/9002/051	16.10.2002	12-10-90-90-00
ORG 531	Anti-Parietal Cell	"other devices"	DE/CA33/9002/052	16.10.2002	12-10-90-11-00
ORG 534A	Anti-Gliadin IgA	"other devices"	DE/CA33/9002/053	16.10.2002	12-10-90-06-00
ORG 534G	Anti-Gliadin IgG	"other devices"	DE/CA33/9002/054	16.10.2002	12-10-90-06-00
ORG 535	Anti-Phosphatidyl Serine IgG/IgM	"other devices"	DE/CA33/9002/055	16.10.2002	12-10-90-03-00
ORG 536	Anti-Phosphatidyl Inositol IgG/IgM	"other devices"	DE/CA33/9002/056	16.10.2002	12-10-90-90-00
ORG 537	Anti-Phosphatidic Acid IgG/IgM	"other devices"	DE/CA33/9002/057	16.10.2002	12-10-90-90-00
ORG 538	ANAScreen	"other devices"	DE/CA33/9002/058	16.10.2002	12-10-01-01-00
ORG 539	ANACombi	"other devices"	DE/CA33/9002/059	16.10.2002	12-10-01-90-00
ORG 540A	Anti-Tissue-Transglutaminase IgA	"other devices"	DE/CA33/9002/060	16.10.2002	12-10-90-21-00
ORG 540G	Anti-Tissue-Transglutaminase IgG	"other devices"	DE/CA33/9002/061	16.10.2002	12-10-90-21-00
ORG 541	Anti-Prothrombin IgG/IgM	"other devices"	DE/CA33/9002/062	16.10.2002	12-10-90-90-00
ORG 541A	Anti-Prothrombin IgA	"other devices"	DE/CA33/9002/063	16.10.2002	12-10-90-90-00
ORG 541S	Anti-Prothrombin Screen	"other devices"	DE/CA33/9002/064	16.10.2002	12-10-90-90-00
ORG 544	ENA-4-Profile	"other devices"	DE/CA33/9002/065	16.10.2002	12-10-01-90-00
ORG 546	ENA-6-Profile	"other devices"	DE/CA33/9002/066	16.10.2002	12-10-01-90-00
ORG 550	Anti-GBM	"other devices"	DE/CA33/9002/067	16.10.2002	12-10-90-15-00
ORG 555	ThromboCombo IgG/IgM	"other devices"	DE/CA33/9002/068	16.10.2002	12-10-90-90-00
ORG 5BM	beta-2-Microglobulin	"other devices"	DE/CA33/9002/071	16.10.2002	12-03-90-02-00
ORG 5FE	Ferritin	"other devices"	DE/CA33/9002/072	16.10.2002	12-07-01-02-00
ORG 5MA	Micro-Albumin	"other devices"	DE/CA33/9002/073	16.10.2002	12-12-90-90-00
ORG 5TG	Thyroglobulin	"other devices"	DE/CA33/9002/074	16.10.2002	12-04-01-08-00
ORG 600	ANA Detect	"other devices"	DE/CA33/9002/075	16.10.2002	12-10-01-01-00
ORG 604	Anti-dsDNA	"other devices"	DE/CA33/9002/076	16.10.2002	12-10-01-05-00
ORG 604A	Anti-dsDNA IgA	"other devices"	DE/CA33/9002/077	16.10.2002	12-10-01-05-00
ORG 604M	Anti-dsDNA IgM	"other devices"	DE/CA33/9002/078	16.10.2002	12-10-01-05-00
ORG 604S	Anti-dsDNA Screen	"other devices"	DE/CA33/9002/079	16.10.2002	12-10-01-05-00
ORG 605	Anti-ssDNA	"other devices"	DE/CA33/9002/080	16.10.2002	12-10-01-06-00
ORG 632	Anti-RNP-70	"other devices"	DE/CA33/9002/081	16.10.2002	12-10-01-14-00
ORG 633	Anti-Centromere B	"other devices"	DE/CA33/9002/082	16.10.2002	12-10-01-15-00
ORG 642	Anti-alpha-Fodrin IgG/IgA	"other devices"	DE/CA33/9002/083	16.10.2002	12-10-01-90-00

ORG 643	Anti-Annexin V IgG/IgM	"other devices"	DE/CA33/9002/084	16.10.2002	12-10-90-90-00
ORG 652	Anti-SS-A 52	"other devices"	DE/CA33/9002/085	16.10.2002	12-10-01-12-00
ORG 660	Anti-SS-A 60	"other devices"	DE/CA33/9002/086	16.10.2002	12-10-01-12-00
ORG 710	ANA-9-Line	"other devices"	DE/CA33/9002/087	16.10.2002	12-10-01-90-00
ORG 545	ASCA IgG/IgA	"other devices"	DE/CA33/9002/089	12.12.2003	12-10-90-19-00
ORG 647	Anti-Intrinsic Factor	"other devices"	DE/CA33/9002/090	12.12.2003	12-10-90-90-00
ORG 590	DNase Activity	"other devices"	DE/CA33/9002/091	12.12.2003	12-10-01-16-00
ORG 711	Nucleo-9-Line	"other devices"	DE/CA33/9002/092	30.04.2004	12-10-01-90-00
ORG 740	Gastro-5-Line	"other devices"	DE/CA33/9002/093	30.04.2004	12-10-90-90-00
ORG 549	Anti-C1q	"other devices"	DE/CA33/9002/094	14.01.2005	12-10-01-16-00
ORG 534S	Anti-Gliadin Screen	"other devices"	DE/CA33/9002/095	14.01.2005	12-10-90-06-00
ORG 540S	Anti-Tissue-Transglutaminase Screen	"other devices"	DE/CA33/9002/096	14.01.2005	12-10-90-21-00
ORG 829	APCA Positive Control	"other devices"	DE/CA33/9002/127	18.05.2005	12-50-01-14-00
ORG 870	Anti-Nuclear Antibodies HEp-2 (ANA-HEp-2)	"other devices"	DE/CA33/9002/146	18.05.2005	12-10-01-01-00
ORG 871	Anti-nDNA Antibodies (nDNA)	"other devices"	DE/CA33/9002/147	25.05.2005	12-10-01-05-00
ORG 872	Anti-Endomysium Antibodies (AEA)	"other devices"	DE/CA33/9002/148	25.05.2005	12-10-90-16-00
ORG 874	Autoantibodies RL/RK/RS	"other devices"	DE/CA33/9002/150	25.05.2005	12-10-90-90-00
ORG 877	Anti-Smooth Muscle Antibodies (ASMA)	"other devices"	DE/CA33/9002/153	25.05.2005	12-10-90-90-00
ORG 801	Anti-nDNA Antibodies (nDNA)	"other devices"	DE/CA33/9002/100	30.05.2005	12-10-01-05-00
ORG 800	Anti-Nuclear Antibodies HEp-2 (ANA-HEp-2)	"other devices"	DE/CA33/9002/101	30.05.2005	12-10-01-01-00
ORG 818	AEA Positive Control	"other devices"	DE/CA33/9002/116	30.05.2005	12-50-01-14-00
ORG 823	AMA Positive Control	"other devices"	DE/CA33/9002/121	30.05.2005	12-50-01-14-00
ORG 824	ANA-Centromere Positive Control	"other devices"	DE/CA33/9002/122	30.05.2005	12-50-01-14-00
ORG 825	ANA-HEp-2 Positive Control	"other devices"	DE/CA33/9002/123	30.05.2005	12-50-01-14-00
ORG 826	ANA-RL Positive Control	"other devices"	DE/CA33/9002/124	30.05.2005	12-50-01-14-00
ORG 827	ANA-Nucleolar Positive Control	"other devices"	DE/CA33/9002/125	30.05.2005	12-50-01-14-00
ORG 828	ANA-Speckled Positive Control	"other devices"	DE/CA33/9002/126	30.05.2005	12-50-01-14-00
ORG 833	ASMA Positive Control	"other devices"	DE/CA33/9002/131	30.05.2005	12-50-01-14-00
ORG 835	nDNA Positive Control	"other devices"	DE/CA33/9002/133	30.05.2005	12-50-01-14-00
ORG 844	Negative Control	"other devices"	DE/CA33/9002/134	30.05.2005	12-50-01-14-00
ORG 837	IgG FITC/Evans	"other devices"	DE/CA33/9002/136	30.05.2005	12-90-90-90-00
ORG 840	IgA FITC/Evans	"other devices"	DE/CA33/9002/137	30.05.2005	12-90-90-90-00
ORG 839	FITC/Evans (R)	"other devices"	DE/CA33/9002/139	30.05.2005	12-90-90-90-00
ORG 842	Mounting Medium	"other devices"	DE/CA33/9002/141	30.05.2005	12-90-90-90-00
ORG 845	Blotting Paper 1 x 12	"other devices"	DE/CA33/9002/143	30.05.2005	12-90-90-90-00
ORG 846	Blotting Paper 1 x 8	"other devices"	DE/CA33/9002/144	30.05.2005	12-90-90-90-00
ORG 847	Blotting Paper 1 x 4	"other devices"	DE/CA33/9002/145	30.05.2005	12-90-90-90-00
ORG 804	Autoantibodies RL/RK/RS	"other devices"	DE/CA33/9002/97	30.05.2005	12 10 90 90 00
ORG 802	Anti-Endomysium Antibodies (AEA)	"other devices"	DE/CA33/9002/99	30.05.2005	12 10 90 16 00
ORG 789	ANCA-3-Line	"other devices"	DE/CA33/9002/162	17.06.2005	12-10-90-90-00
ORG 548	Anti-MCV	"other devices"	DE/CA33/ORG/9002/163	10.08.2005	12-11-01-90-00
ORG 300-00	ALEGRIA	"other devices"	DE/CA33/ORG/9002/168	22.11.2005	22 03 03
ORG 200	ANA Detect	"other devices"	DE/CA33/ORG/9002/169	22.11.2005	12-10-01-01-00
ORG 202	Anti-TG	"other devices"	DE/CA33/ORG/9002/170	22.11.2005	12-10-03-04-00
ORG 203	Anti-TPO	"other devices"	DE/CA33/ORG/9002/171	22.11.2005	12-10-03-01-00
ORG 204A	Anti-dsDNA IgA	"other devices"	DE/CA33/ORG/9002/172	22.11.2005	12-10-01-05-00
ORG 204G	Anti-dsDNA IgG	"other devices"	DE/CA33/ORG/9002/173	22.11.2005	12-10-01-05-00
ORG 204M	Anti-dsDNA IgM	"other devices"	DE/CA33/ORG/9002/174	22.11.2005	12-10-01-05-00
ORG 204S	Anti-dsDNA Screen	"other devices"	DE/CA33/ORG/9002/175	22.11.2005	12-10-01-05-00
ORG 205	Anti-ssDNA	"other devices"	DE/CA33/ORG/9002/176	22.11.2005	12-10-01-06-00
ORG 206	ENAscreen	"other devices"	DE/CA33/ORG/9002/177	22.11.2005	12-10-01-02-00
ORG 207	Anti-Histone	"other devices"	DE/CA33/ORG/9002/178	22.11.2005	12-10-01-07-00
ORG 208	Anti-SS-A	"other devices"	DE/CA33/ORG/9002/179	22.11.2005	12-10-01-12-00
ORG 209	Anti-SS-B	"other devices"	DE/CA33/ORG/9002/180	22.11.2005	12-10-01-13-00
ORG 210	Anti-Sm	"other devices"	DE/CA33/ORG/9002/181	22.11.2005	12-10-01-11-00
ORG 211	Anti-RNP/Sm	"other devices"	DE/CA33/ORG/9002/182	22.11.2005	12-10-01-14-00

ORG 212	Anti-Scl-70	"other devices"	DE/CA33/ORG/9002/183	22.11.2005	12-10-01-10-00
ORG 213	Anti-Jo-1	"other devices"	DE/CA33/ORG/9002/184	22.11.2005	12-10-01-08-00
ORG 215A	Anti-Cardiolipin IgA	"other devices"	DE/CA33/ORG/9002/185	22.11.2005	12-10-90-01-00
ORG 215G	Anti-Cardiolipin IgG	"other devices"	DE/CA33/ORG/9002/186	22.11.2005	12-10-90-01-00
ORG 215M	Anti-Cardiolipin IgM	"other devices"	DE/CA33/ORG/9002/187	22.11.2005	12-10-90-01-00
ORG 215S	Anti-Cardiolipin Screen	"other devices"	DE/CA33/ORG/9002/188	22.11.2005	12-10-90-01-00
ORG 216	AMA-M2	"other devices"	DE/CA33/ORG/9002/189	22.11.2005	12-10-90-02-00
ORG 217	Anti-Rib-P	"other devices"	DE/CA33/ORG/9002/190	22.11.2005	12-10-90-20-00
ORG 218	Anti-PR3	"other devices"	DE/CA33/ORG/9002/191	22.11.2005	12-10-90-10-00
ORG 219	Anti-MPO	"other devices"	DE/CA33/ORG/9002/192	22.11.2005	12-10-90-09-00
ORG 220	Anti-Insulin	"other devices"	DE/CA33/ORG/9002/193	22.11.2005	12-06-01-04-00
ORG 221A	Anti-beta-2-ORgGlycoprotein I IgA	"other devices"	DE/CA33/ORG/9002/194	22.11.2005	12-10-90-04-00
ORG 221G	Anti-beta-2-Glycoprotein I IgG	"other devices"	DE/CA33/ORG/9002/195	22.11.2005	12-10-90-04-00
ORG 221M	Anti-beta-2-Glycoprotein I IgM	"other devices"	DE/CA33/ORG/9002/196	22.11.2005	12-10-90-04-00
ORG 221S	Anti-beta-2-Glycoprotein I Screen	"other devices"	DE/CA33/ORG/9002/197	22.11.2005	12-10-90-04-00
ORG 222A	Rheumatoid Factor IgA	"other devices"	DE/CA33/ORG/9002/198	22.11.2005	12-11-01-10-00
ORG 222G	Rheumatoid Factor IgG	"other devices"	DE/CA33/ORG/9002/199	22.11.2005	12-11-01-10-00
ORG 222M	Rheumatoid Factor IgM	"other devices"	DE/CA33/ORG/9002/200	22.11.2005	12-11-01-10-00
ORG 222S	Rheumatoid Factor Screen	"other devices"	DE/CA33/ORG/9002/201	22.11.2005	12-11-01-10-00
ORG 223	Anti-BPI	"other devices"	DE/CA33/ORG/9002/202	22.11.2005	12-10-90-90-00
ORG 224	Anti-Elastase	"other devices"	DE/CA33/ORG/9002/203	22.11.2005	12-10-90-90-00
ORG 225	Anti-Cathepsin G	"other devices"	DE/CA33/ORG/9002/204	22.11.2005	12-10-90-90-00
ORG 226	Anti-Lysozyme	"other devices"	DE/CA33/ORG/9002/205	22.11.2005	12-10-90-90-00
ORG 227	Anti-Lactoferrin	"other devices"	DE/CA33/ORG/9002/206	22.11.2005	12-10-90-90-00
ORG 228	Anti-Nucleosome	"other devices"	DE/CA33/ORG/9002/207	22.11.2005	12-10-90-18-00
ORG 229G	Anti-Phospholipid Screen IgG	"other devices"	DE/CA33/ORG/9002/208	22.11.2005	12-10-90-90-00
ORG 229M	Anti-Phospholipid Screen IgM	"other devices"	DE/CA33/ORG/9002/209	22.11.2005	12-10-90-90-00
ORG 231	Anti-Parietal Cell	"other devices"	DE/CA33/ORG/9002/210	22.11.2005	12-10-90-11-00
ORG 232	Anti-RNP-70	"other devices"	DE/CA33/ORG/9002/211	22.11.2005	12-10-01-14-00
ORG 233	Anti-Centromere B	"other devices"	DE/CA33/ORG/9002/212	22.11.2005	12-10-01-15-00
ORG 234A	Anti-Gliadin IgA	"other devices"	DE/CA33/ORG/9002/213	22.11.2005	12-10-90-06-00
ORG 234G	Anti-Gliadin IgG	"other devices"	DE/CA33/ORG/9002/214	22.11.2005	12-10-90-06-00
ORG 234S	Anti-Gliadin Screen	"other devices"	DE/CA33/ORG/9002/215	22.11.2005	12-10-90-06-00
ORG 235G	Anti-Phosphatidyl Serine IgG	"other devices"	DE/CA33/ORG/9002/216	22.11.2005	12-10-90-03-00
ORG 235M	Anti-Phosphatidyl Serine IgM	"other devices"	DE/CA33/ORG/9002/217	22.11.2005	12-10-90-03-00
ORG 236G	Anti-Phosphatidyl Inositol IgG	"other devices"	DE/CA33/ORG/9002/218	22.11.2005	12-10-90-90-00
ORG 236M	Anti-Phosphatidyl Inositol IgM	"other devices"	DE/CA33/ORG/9002/219	22.11.2005	12-10-90-90-00
ORG 237G	Anti-Phosphatidic Acid IgG	"other devices"	DE/CA33/ORG/9002/220	22.11.2005	12-10-90-90-00
ORG 237M	Anti-Phosphatidic Acid IgM	"other devices"	DE/CA33/ORG/9002/221	22.11.2005	12-10-90-90-00
ORG 238	ANAscreen	"other devices"	DE/CA33/ORG/9002/222	22.11.2005	12-10-01-01-00
ORG 240A	Anti-Tissue-Transglutaminase IgA	"other devices"	DE/CA33/ORG/9002/223	22.11.2005	12-10-90-21-00
ORG 240G	Anti-Tissue-Transglutaminase IgG	"other devices"	DE/CA33/ORG/9002/224	22.11.2005	12-10-90-21-00
ORG 240S	Anti-Tissue-Transglutaminase Screen	"other devices"	DE/CA33/ORG/9002/225	22.11.2005	12-10-90-21-00
ORG 241A	Anti-Prothrombin IgA	"other devices"	DE/CA33/ORG/9002/226	22.11.2005	12-10-90-90-00
ORG 241G	Anti-Prothrombin IgG	"other devices"	DE/CA33/ORG/9002/227	22.11.2005	12-10-90-90-00
ORG 241M	Anti-Prothrombin IgM	"other devices"	DE/CA33/ORG/9002/228	22.11.2005	12-10-90-90-00
ORG 241S	Anti-Prothrombin Screen	"other devices"	DE/CA33/ORG/9002/229	22.11.2005	12-10-90-90-00
ORG 242A	Anti-alpha-Fodrin IgA	"other devices"	DE/CA33/ORG/9002/230	22.11.2005	12-10-01-90-00
ORG 242G	Anti-alpha-Fodrin IgG	"other devices"	DE/CA33/ORG/9002/231	22.11.2005	12-10-01-90-00
ORG 243G	Anti-Annexin V IgG	"other devices"	DE/CA33/ORG/9002/232	22.11.2005	12-10-90-90-00
ORG 243M	Anti-Annexin V IgM	"other devices"	DE/CA33/ORG/9002/233	22.11.2005	12-10-90-90-00
ORG 245A	ASCA IgA	"other devices"	DE/CA33/ORG/9002/234	22.11.2005	12-10-90-19-00
ORG 245G	ASCA IgG	"other devices"	DE/CA33/ORG/9002/235	22.11.2005	12-10-90-19-00
ORG 247	Anti-Intrinsic Factor	"other devices"	DE/CA33/ORG/9002/236	22.11.2005	12-10-90-90-00
ORG 248	Anti-MCV®	"other devices"	DE/CA33/ORG/9002/237	22.11.2005	12-11-01-90-00
ORG 249	Anti-C1q	"other devices"	DE/CA33/ORG/9002/238	22.11.2005	12-10-01-16-00

ORG 250	Anti-GBM	"other devices"	DE/CA33/ORG/9002/239	22.11.2005	12-10-90-15-00
ORG 252	Anti-SS-A 52	"other devices"	DE/CA33/ORG/9002/240	22.11.2005	12-10-01-12-00
ORG 260	Anti-SS-A 60	"other devices"	DE/CA33/ORG/9002/241	22.11.2005	12-10-01-12-00
ORG 843	PBS (10x)	"other devices"	DE/CA33/ORG/9002/142/1	29.08.2006	12 90 90 90 00
ORG 849	IgG FITC/Evans (M)	"other devices"	DE/CA33/ORG/2007/2	31.01.2007	12-90-90-90-00
ORG 618	Anti-PR3 hs	"other devices"	DE/CA33/ORG/9002/102/1AE	31.01.2007	12-10-90-10-00
ORG 310	Alegria® Positive Control	"other devices"	DE/CA33/ORG/2007/3	23.07.2007	12-50-01-90-00
ORG 311	Alegria® Negative Control	"other devices"	DE/CA33/ORG/2007/4	23.07.2007	12-50-01-90-00
ORG 170	rheumachec®	"other devices"	DE/CA33/ORG2007/5	02.11.2007	12 11 01 90 00
ORG 712	PM-Scl Blot	"other devices"	DE/CA33/ORG/2008/1	16.01.2008	12-11-01-90-00
ORG 760	Myositis plus	"other devices"	DE/CA33/ORG/2008/3	03.04.2008	12-10-01-90-00
ORG 318	Anti-PR3 hs	"other devices"	DE/CA33/ORG/2008/5	23.04.2008	12-12-01-90-00
ORG 551A	Anti-DGP IgA	"other devices"	DE/CA33/ORG/2009/1	14.10.2009	12-10-90-06-00
ORG 551G	Anti-DGP IgG	"other devices"	DE/CA33/ORG/2009/2	14.10.2009	12-10-90-06-00
ORG 551S	Anti-DGP Screen	"other devices"	DE/CA33/ORG/2010/1	23.06.2010	12-10-90-06-00
ORG 504	Anti-dsDNA IgG	"other devices"	DE/CA33/ORG/2010/4	12.11.2010	12 10 01 05 00
ORG 908MX	Anti-Mumps Virus IgM Abs.	"other devices"	DE/CA33/ORG/2010/11	06.01.2011	15 04 80 08
ORG 909G	Anti-Measles Virus IgG	"other devices"	DE/CA33/ORG/2010/12	06.01.2011	15 04 80 07
ORG 909MX	Anti-Measles Virus IgM Abs.	"other devices"	DE/CA33/ORG/2010/14	06.01.2011	15 04 80 07
ORG 901G	Anti-EBV (VCA) IgG	"other devices"	DE/CA33/ORG/2010/5	06.01.2011	15 04 04 04
ORG 901MX	Anti-EBV (VCA) IgM Abs.	"other devices"	DE/CA33/ORG/2010/7	06.01.2011	15 04 04 04
ORG 902	Anti-EBV (EBNA-1) IgG	"other devices"	DE/CA33/ORG/2010/8	06.01.2011	15 04 04 04
ORG 908G	Anti-Mumps Virus IgG	"other devices"	DE/CA33/ORG/2010/9	06.01.2011	15 04 80 08
ORG 251G	Anti-DGP IgG	"other devices"	DE/CA33/ORG/2011/1	24.01.2011	12 10 90 06 00
ORG 251A	Anti-DGP IgA	"other devices"	DE/CA33/ORG/2011/2	24.01.2011	12 10 90 06 00
ORG 251S	Anti-DGP Screen	"other devices"	DE/CA33/ORG/2011/6	11.04.2011	12 10 90 06 00
ORG 903MX	Anti-HSV-1 IgM Abs.	"other devices"	DE/CA33/ORG/2011/11	09.08.2011	15 04 03 06 00
ORG 904G	Anti-HSV-2 IgG	"other devices"	DE/CA33/ORG/2011/12	09.08.2011	15 04 03 05 00
ORG 904MX	Anti-HSV-2 IgM Abs.	"other devices"	DE/CA33/ORG/2011/14	09.08.2011	15 04 03 06 00
ORG 905G	Anti-HSV-1/2 IgG	"other devices"	DE/CA33/ORG/2011/15	09.08.2011	15 04 03 05 00
ORG 905MX	Anti-HSV-1/2 IgM Abs.	"other devices"	DE/CA33/ORG/2011/17	09.08.2011	15 04 03 06 00
ORG 910	Anti-EBV (ZEBRA) IgM	"other devices"	DE/CA33/ORG/2011/18	09.08.2011	15 04 04 04 00
ORG 301	Anti-CCP hs (high sensitive)®	"other devices"	DE/CA33/ORG/2011/7	09.08.2011	12 11 01 90 00
ORG 601	Anti-CCP hs (high sensitive)®	"other devices"	DE/CA33/ORG/2011/8	09.08.2011	12 11 01 90 00
ORG 903G	Anti-HSV-1 IgG	"other devices"	DE/CA33/ORG/2011/9	09.08.2011	15 04 03 05 00
ORG 253	Anti-LKM-1	"other devices"	DE/CA33/ORG/2011/21	05.01.2012	12-10-90-08-00
ORG 254	Anti-Sp100	"other devices"	DE/CA33/ORG/2011/22	05.01.2012	12-10-90-12-00
ORG 256	Anti-gp210	"other devices"	DE/CA33/ORG/2011/23	05.01.2012	none
ORG 257	Anti-SLA	"other devices"	DE/CA33/ORG/2011/24	05.01.2012	12-10-90-17-00
ORG 911G	Anti-Borrelia IgG	"other devices"	DE/CA33/ORG/2012/09	23.10.2012	15-01-06-05-00
ORG 911MX	Anti-Borrelia IgM Abs.	"other devices"	DE/CA33/ORG/2012/10	23.10.2012	15-01-06-06-00
ORG 912G	Anti-Parvovirus B19 IgG	"other devices"	DE/CA33/ORG/2012/11	23.10.2012	15-04-80-09-00
ORG 912MX	Anti-Parvovirus B19 IgM Abs.	"other devices"	DE/CA33/ORG/2012/12	23.10.2012	15-04-80-09-00
ORG 270	25-OH Vitamin D3/D2	"other devices"	DE/CA33/ORG/2013/1	18.04.2013	12-06-03-10-00
ORG 389	ANCAscreen hs (high sensitive)	"other devices"	DE/CA33/ORG/2013/2	18.04.2013	none
ORG 689	ANCAscreen hs (high sensitive)	"other devices"	DE/CA33/ORG/2013/3	18.04.2013	none
ORG 913A	Anti-Yersinia IgA	"other devices"	DE/CA33/ORG/2013/4	18.04.2013	15-01-90-06-00
ORG 913G	Anti-Yersinia IgG	"other devices"	DE/CA33/ORG/2013/5	18.04.2013	15-01-90-06-00
ORG 914A	Anti-VZV IgA	"other devices"	DE/CA33/ORG/2013/6	18.04.2013	15-04-80-10-00
ORG 914G	Anti-VZV IgG	"other devices"	DE/CA33/ORG/2013/7	18.04.2013	15-04-80-10-00
ORG 914MX	Anti-VZV IgM Abs.	"other devices"	DE/CA33/ORG/2013/8	18.04.2013	15-04-80-10-00
ORG 271	25-OH Vitamin D3/D2 Control Set	"other devices"	DE/CA33/ORG/2013/11	08.11.2013	12-50-01-12-00
ORG 280	Calprotectin	"other devices"	DE/CA33/ORG/2013/9	08.11.2013	11-70-03-90-00
ORG 916A	Anti-B. pertussis Toxin IgA	"other devices"	DE/CA33/ORG/2014/1	08.01.2014	15-01-90-07-00
ORG 916G	Anti-B. pertussis Toxin IgG	"other devices"	DE/CA33/ORG/2014/2	08.01.2014	15-01-90-07-00
ORG 915A	Anti-Mycoplasma pneumoniae IgA	"other devices"	DE/CA33/ORG/2014/3	08.01.2014	15-01-08-03-00

ORG 915G	Anti-Mycoplasma pneumoniae IgG	"other devices"	DE/CA33/ORG/2014/4	08.01.2014	15-01-08-03-00
ORG 915MX	Anti-Mycoplasma pneumoniae IgM Abs.	"other devices"	DE/CA33/ORG/2014/5	08.01.2014	15-01-08-03-00
ORG 917A	Anti-Helicobacter pylori IgA	"other devices"	DE/CA33/ORG/2014/6	08.01.2014	15-01-04-03-00
ORG 917G	Anti-Helicobacter pylori IgG	"other devices"	DE/CA33/ORG/2014/7	08.01.2014	15-01-04-03-00
ORG 722	Liver-9-Line 2nd Generation	"other devices"	DE/CA33/ORG/2014/8	31.01.2014	12-12-01-90-00
ORG 892	Anti-Neutrophil Cytoplasmic Antibodies (ANCA-Formalin)	"other devices"	DE/CA33/ORG/2014/10	06.03.2014	none
ORG 891	Anti-Neutrophil Cytoplasmic Antibodies (ANCA-Ethanol)	"other devices"	DE/CA33/ORG/2014/9	06.03.2014	none
R 515S	Anti-Cardiolipin Screen Control Set	"other devices"	DE/CA33/ORG/2011/19/1	09.07.2014	12 50 01 14 00
R 521S	Anti-beta-2-Glycoprotein I Screen Control Set	"other devices"	DE/CA33/ORG/2011/20/2	09.07.2014	12 50 01 14 00
ORG 580	Calprotectin	"other devices"	DE/CA33/ORG/2014/11	14.08.2014	11-70-03-90-00
ORG 914GL	Anti-VZV IgG Liquor	"other devices"	DE/CA33/ORG/2015/1	23.03.2015	15-04-80-10-00
ORG 919GL	Anti-Rubella Virus IgG Liquor	"other devices"	DE/CA33/ORG/2015/2	23.03.2015	15-04-01-90-00
ORG 909GL	Anti-Measles Virus IgG Liquor	"other devices"	DE/CA33/ORG/2015/3	23.03.2015	15-04-80-07-00
ORG 911GL	Anti-Borrelia IgG Liquor	"other devices"	DE/CA33/ORG/2015/4	23.03.2015	15-01-06-05-00
ORG 911ML	Anti-Borrelia IgM Liquor	"other devices"	DE/CA33/ORG/2015/5	23.03.2015	15-01-06-06-00
F5126	Stool Extraction Medium	"other devices"	DE/CA33/ORG/2015/6	16.04.2015	15-90-90-01-00
ORG 284	Lactoferrin	"other devices"	DE/CA33/ORG/2015/7	16.04.2015	12-01-03-05-00
ORG 570	25-OH Vitamin D3/D2	"other devices"	DE/CA33/ORG/2015/8	27.07.2015	12-06-03-10-00
ORG 258	Anti-LC1	"other devices"	DE/CA33/ORG/2015/9	08.09.2015	12-10-90-08-00
ORG 921G	Anti-Hepatitis E Virus IgG	"other devices"	DE/CA33/ORG/2015/10	02.11.2015	15-02-05-05-00
ORG 921MX	Anti-Hepatitis E Virus IgM Abs.	"other devices"	DE/CA33/ORG/2015/11	02.11.2015	15-02-05-06-00
ORG 901GL	Anti-EBV (VCA) IgG Liquor	"other devices"	DE/CA33/ORG/2015/12	04.12.2015	15-04-04-04-00
ORG 905GL	Anti-HSV-1/2 IgG Liquor	"other devices"	DE/CA33/ORG/2015/13	04.12.2015	15-04-03-05-00
ORG 286	Alpha-1-Antitrypsin	"other devices"	DE/CA33/ORG/2016/1	18.08.2016	12-01-90-02-00