

Sugentech, Inc., Korea	FORM List of CE Marked Products (IVD) (Annex Ia of the Authorized Representative Agreement)	MTPC DOC. No.: FB 07.05.14 Revision 00 Valid from 01.10.2015
-----------------------------------	--	--

Last update of the list: 2020-11-05 New products are marked in green / Obsolete products in red				Current number of categories: 21		Number of categories defined in agreement: 5			
Internal Adm.-No.AR	Registration Number German CA: DE/CA70/40838...	Cataloge No.	Product name (Model name)	Indications (Intended use)	EDMA-Code [GMDN-Code]	EDMA-Description (Product category)	Applied Annex	Declaration of Conformity Date	CE-Mark (Notification at CA)

To be filled by MTPC	To be filled by MTPC								To be filled by MTPC
SUG-01	138137 Notification of Change (due to new address): 145202	CRPT010E, CRPT020E, CRPT025E, CRPT030E, CRPT050E, CRPT100E	INCLIX™ CRP	INCLIX™ CRP along with INCLIX™ Analyzer is an immunoassay for quantitative determination of C-Reactive Protein (CRP) in serum, plasma and whole blood.	12 11 01 09 00	C-Reactive Protein	Annex III	01.10.2016 Revised: 12.06.2018	13.10.2016 Notification of Change: 21.08.2018
SUG-01-01	Covered by 138137 Notification of Change (due to new address): 145202	HCRT010E, HCRT020E, HCRT025E, HCRT030E, HCRT050E, HCRT100E	INCLIX™ hsCRP	INCLIX™ hsCRP along with INCLIX™ Analyzer is an immunoassay for quantitative determination of high sensitivity C-Reactive Protein (hsCRP) in serum, plasma and whole blood.	12 11 01 09 00	C-Reactive Protein	Annex III	01.03.2017 Revised: 12.06.2018	Covered by notification 13.10.2016 Notification of Change: 21.08.2018
SUG-01-02	Covered by 138137 Notification of Change (due to new address): 145202	DCRT010E, DCRT020E, DCRT025E, DCRT030E, DCRT050E, DCRT100E	INCLIX™ dual CRP	INCLIX™ dual CRP along with INCLIX™ Analyzer is an immunoassay for quantitative determination of C-Reactive Protein (CRP) in serum, plasma and whole blood.	12 11 01 09 00	C-Reactive Protein	Annex III	01.03.2017 Revised: 12.06.2018	Covered by notification 13.10.2016 Notification of Change: 21.08.2018
SUG-02	138138 Notification of Change (due to new address): 145203	PCTT010E, PCTT020E, PCTT025E, PCTT030E, PCTT050E, PCTT100E	INCLIX™ PCT	INCLIX™ PCT along with INCLIX™ Analyzer is an immunoassay for quantitative determination of Procalcitonin (PCT) in human serum/plasma.	12 06 90 16 00	Procalcitonin	Annex III	01.10.2016 Revised: 12.06.2018	14.10.2016 Notification of Change: 21.08.2018
SUG-03	138364 Notification of Change (due to new address): 145204 Notification of Change (add new prod.): 150137	SGT-i16	INCLIX™	The INCLIX™ is an analyzer for quantitative and qualitative determination of analytes by capturing and analyzing the image of test result for lateral flow Immunoassay.	22 03 01	Manual I.A. Instruments / Readers	Annex III	01.10.2016 Revised: 12.06.2018	08.11.2016 Notification of Change: 21.08.2018 Notification of Change: 11.07.2019

Internal Adm.-No.AR	Registration Number German CA: DE/CA70/40838...	Cataloge No.	Product name (Model name)	Indications (Intended use)	EDMA-Code [GMDN-Code]	EDMA-Description (Product category)	Applied Annex	Declaration of Conformity Date	CE-Mark (Notification at CA)
SUG-03-01	150137	/	EASY CHECK F-100 (Immunofluorescence Analyzer)	The EASY CHECK F-100 is a device that analyzes the membrane of devices that have been tested for reactions to measure concentrations of antigens or antibodies.	22 03 01	Manual I.A. Instruments / Readers	Annex III	2019-04-30	2019-07-11
SUG-04 (+SUG-05)	139446 Notification of Change (due to new address): 00145677		Surearly™ Digital Pregnancy Test	Surearly™ Digital Pregnancy Test is an in vitro diagnostic medical device for the rapid determination of human chorionic gonadotropin (hCG) in urine. The tests are for the qualitative detection of hCG to aid in the early determination of pregnancy. They are intended for non-professional, over-the-counter (OTC) use only.	22 03 02	Semi-automated I.A. Systems	Self-Testing	01.11.2015 Revised: 18.05.2018	07.02.2017 Notification of Change: 19.09.2018
SUG-04-01 (+SUG-05-03)	139446 Notification of Change (due to new address): 00145677		Surearly™ Digital Multi Use Pregnancy Test	Surearly™ Digital Multi Use Pregnancy Test is an in vitro diagnostic medical device for the rapid determination of hCG in urine. The test is for the qualitative detection of hCG to aid in the early determination of pregnancy. It is intended for non-professional, over-the-counter (OTC) use only.	22 03 02	Semi-automated I.A. Systems	Self-Testing	01.11.2015 Revised: 18.05.2018	07.02.2017 Notification of Change: 19.09.2018
SUG-04-02 (+SUG-06)	139446 Notification of Change (due to new address): 00145677		Surearly™ Digital Ovulation Test	Surearly Digital Ovulation Test is an in vitro diagnostic medical device for the rapid determination of Luteinizing Hormone (LH) in urine. The test is for the qualitative detection of LH to predict a woman's most fertile period. It is intended for non-professional, over-the-counter (OTC) use only.	22 03 02	Semi-automated I.A. Systems	Self-Testing	01.11.2015 Revised: 18.05.2018	07.02.2017 Notification of Change: 19.09.2018
SUG-05	139447 Notification of Change (due to new address): 00145678		Surearly™ Pregnancy Test Strip (Surearly™ Digital Pregnancy Test)	Surearly Pregnancy Test Strip is an in vitro diagnostic medical device for the rapid determination of human chorionic gonadotropin (hCG) in urine. The test is for the qualitative detection of hCG to aid in the determination of pregnancy. It is intended for non-professional, over-the-	12 70 05 02 00	HCG - Rapid Test	Self-Testing	01.11.2015 Revised: 18.05.2018	07.02.2017 Notification of Change: 19.09.2018

Internal Adm.-No.AR	Registration Number German CA: DE/CA70/40838...	Cataloge No.	Product name (Model name)	Indications (Intended use)	EDMA-Code [GMDN-Code]	EDMA-Description (Product category)	Applied Annex	Declaration of Conformity Date	CE-Mark (Notification at CA)
SUG-05-01	139447 Notification of Change (due to new address): 00145678		Surearly™ Easy Pregnancy Test	Surearly™ Easy Pregnancy Test is an in vitro diagnostic medical device for the rapid determination of human chorionic gonadotropin (hCG) in urine. The test is for the qualitative detection of hCG to aid in the early determination of pregnancy. It is intended for over-the-counter (OTC) use only.	12 70 05 02 00	HCG - Rapid Test	Self-Testing	01.11.2015 Revised: 18.05.2018	07.02.2017 Notification of Change: 19.09.2018
SUG-05-02	139447 Notification of Change (due to new address): 00145678		Surearly™ Early Sign Pregnancy Test	Surearly™ Early Sign Pregnancy Test is an in vitro diagnostic medical device for the rapid determination of human chorionic gonadotropin (hCG) in urine. The test is for the qualitative detection of hCG to aid in the early determination of pregnancy. It is intended for over-the-counter (OTC) use only.	12 70 05 02 00	HCG - Rapid Test	Self-Testing	01.11.2015 Revised: 18.05.2018	07.02.2017 Notification of Change: 19.09.2018
SUG-05-03	139447 Notification of Change (due to new address): 00145678		Surearly™ Digital Multi Use Pregnancy Test	Surearly™ Digital Multi Use Pregnancy Test is an in vitro diagnostic medical device for the rapid determination of hCG in urine. The test is for the qualitative detection of hCG to aid in the early determination of pregnancy. It is intended for non-professional, over-the-counter (OTC) use only.	12 70 05 02 00	HCG - Rapid Test	Self-Testing	01.11.2015 Revised: 18.05.2018	07.02.2017 Notification of Change: 19.09.2018
SUG-06	449 Notification of Change (due to registration number): 139703 Notification of Change (due to new address): 00145679		Surearly™ Ovulation Test Strip Surearly™ Digital Ovulation Test	Surearly Ovulation Test Strip is an in vitro diagnostic medical device for the rapid determination of Luteinizing Hormone (LH) in urine. The test is for the qualitative detection of LH to predict a woman's most fertile period. It is intended for non-professional, over-the-counter (OTC) use.	12 70 05 04 00	LH - Rapid Test	Self-Testing	01.11.2015 Revised: 18.05.2018	07.02.2017 Notification of Change: 06.03.2017 Notification of Change: 19.09.2018
SUG-07	00140583 Notification of Change (due to new address): 145205	HBAT010E, HBAT020E, HBAT025E, HBAT030E, HBAT050E, HBAT100E	INCLIX™ HbA1c	INCLIX™ HbA1c along with INCLIX™ Analyzer is an immunoassay for quantitative determination of glycosylated hemoglobin (HbA1c) in whole blood. The test is used as an aid to diagnose diabetes and for monitoring long-term glycemic control in patients with diabetes.	12 06 01 06 00	Glycosylated/Glycosylated Haemoglobin	Annex III	15.06.2017 Revised: 12.06.2018	21.06.2017 Notification of Change: 21.08.2018

Internal Adm.-No.AR	Registration Number German CA: DE/CA70/40838...	Cataloge No.	Product name (Model name)	Indications (Intended use)	EDMA-Code [GMDN-Code]	EDMA-Description (Product category)	Applied Annex	Declaration of Conformity Date	CE-Mark (Notification at CA)
SUG-08	00140584 Notification of Change (due to new address): 145206	TPIT010E, TPIT020E, TPIT025E, TPIT030E, TPIT050E, TPIT100E	INCLIX™ Troponin I	INCLIX™ Troponin I along with INCLIX™ Analyzer is an immunoassay for quantitative determination of cardiac Troponin I (TnI) in serum, plasma and whole blood. The test is used as an aid to diagnose Acute Myocardial Infarction (AMI).	12 70 13 03 00	Troponin I/T - Rapid Test	Annex III	15.06.2017 Revised: 12.06.2018	21.06.2017 Notification of Change: 21.08.2018
SUG-09	00141298 Notification of Change (due to new address): 145207 Notification of Change (add prod): 154680	CT05100E	5µL Capillary tube	5µL capillary tube is an in vitro diagnostic medical device for the collection of capillary blood.	26 09	Other Other Clinical Instruments	Annex III	01.07.2017 Revised: 12.06.2018	23.08.2017 Notification of Change: 21.08.2018 Notification of Change: 30.03.2020
SUG-09-01	154680	CT10300E	pettyPip	pettyPip is a device for the collection and dispensing of blood samples for in vitro diagnostic testing.	26 09	Other Other Clinical Instruments	Annex III	2020-03-26	2020-03-30
SUG-10	00141571 Notification of Change (due to new address): 145208	IFNT010E IFNT020E IFNT025E IFNT030E IFNT050E IFNT100E	SGT i-flex Influenza A&B	SGT i-flex Influenza A&B is an immunoassay for qualitative detection of Influenza virus type A or type B antigens directly from nasopharyngeal swab specimens. The test is used as an aid in the rapid differential diagnosis of influenza A and B viral infection.	15 04 80 04 00	Influenza & Para Influenza	Annex III	15.09.2017 Revised: 12.06.2018	21.09.2017 Notification of Change: 21.08.2018
SUG-11	00142851 Notification of change: 00142881 Notification of Change (due to new address): 145209 Notification of Change (add.new prod.): 145205	ZIKT010E ZIKT020E ZIKT025E ZIKT030E ZIKT050E ZIKT100E	SGT i-flex Zika IgM/IgG	SGT i-flex Zika IgM/IgG Test is an immunoassay for qualitative detection of IgM and IgG antibodies to Zika virus in human Serum/Plasma. The test is useful as a screening test for Zika viral infection.	15 04 80 90 00	Other Viral Antigen/Antibody Detection	other IVD/Annex III	20.12.2017 Revised: 12.06.2018	12.01.2018 Notification of change: 19.01.2018 Notification of Change: 21.08.2018 Notification of Change: 07.05.2019

Internal Adm.-No.AR	Registration Number German CA: DE/CA70/40838...	Cataloge No.	Product name (Model name)	Indications (Intended use)	EDMA-Code [GMDN-Code]	EDMA-Description (Product category)	Applied Annex	Declaration of Conformity Date	CE-Mark (Notification at CA)
SUG-11-01	149025	ZIAT025E	SGT i-flex Zika NS1	SGT i-flex Zika NS1 is a rapid immunochromatographic assay for the detection of NS1 antigen to Zika virus in human serum, plasma and whole blood. The assay is used as screening test for zika viral infection.	15 04 80 90 00	Other Viral Antigen / Antibody Detection	other IVD, Annex III	2019-03-29	2019-05-07
SUG-12	00142833 Notification of Change (due to new address): 145211	BCGT010E BCGT020E BCGT025E BCGT030E BCGT050E BCGT100E	INCLIX™ βhCG	INCLIX™ βhCG along with INCLIX™ Analyzer is an immunoassay for quantitative determination of human Chorionic Gonadotropin (hCG) in serum, plasma and whole blood. The test is used as an aid to diagnose early pregnancy.	12 05 02 06 00	β Human Chorionic Gonadotropin (incl. subunit)	other IVD/Annex III	20.12.2017 Revised: 12.06.2018	12.01.2018 Notification of Change: 21.08.2018
SUG-13	00142835 Notification of Change (due to new address): 145213	IGET010E IGET020E IGET025E IGET030E IGET050E IGET100E	INCLIX™ Total IgE	INCLIX™ Total IgE along with INCLIX™ Analyzer is an immunoassay for quantitative determination of total immunoglobulin E (IgE) in serum or plasma. The test is used as an aid in the diagnosis of IgE mediated allergic disorders.	12 02 01 02 00	Immunoglobulin E - Total	other IVD/Annex III	20.12.2017 Revised: 12.06.2018	12.01.2018 Notification of Change: 21.08.2018
SUG-14	148253	TBCT010E TBCT025E TBCT050E	INCLIX™ Blood TB	The INCLIX™ Blood TB with INCLIX™ analyzer is an immunochromatographic in-vitro diagnostic medical device for qualitative determination of antigen CFP10 of M.tuberculosis and M.bovis in human serum or plasma (Li /Na Heparin /Na citrate)	15 01 07 01 00	Mycobacterial Antigen Detection	other IVD/Annex III	2019-01-31	2019-04-02
SUG-15	150731 Notification of Change (add new prod.): 151958	PCTC001E PCTC002E PCTC003E PCTC004E PCTC005E PCTC006E PCTC007E PCTC008E PCTC009E PCTC010E PCTC011E PCTC012E	INCLIX™ PCT Control	INCLIX™ PCT control is intended to be used for in vitro diagnostic use in the quality control of INCLIX PCT. For in vitro diagnostic use.	12 50 01 06 00	Specific Protein Controls	other IVD/Annex III	2019-07-17	30.08.2019 Notification of Change: 06.12.2019

Internal Adm.-No.AR	Registration Number German CA: DE/CA70/40838...	Cataloge No.	Product name (Model name)	Indications (Intended use)	EDMA-Code [GMDN-Code]	EDMA-Description (Product category)	Applied Annex	Declaration of Conformity Date	CE-Mark (Notification at CA)
SUG-15-01	150731 Notification of Change (add new prod.):151958	CRPC001E CRPC002E CRPC003E CRPC004E CRPC005E CRPC006E CRPC007E CRPC008E CRPC009E CRPC010E CRPC011E CRPC012E	INCLIX™ CRP Control	INCLIX™ CRP control is intended to be used for in vitro diagnostic use in the quality control of INCLIX CRP, dual CRP and hsCRP assay kit. For in vitro diagnostic use.	12 50 01 06 00	Specific Protein Controls	other IVD/Annex III	2019-07-17	30.08.2019 Notification of Change: 06.12.2019
SUG-15-02	150731 Notification of Change (add new prod.):151958	HBAC001E HBAC002E HBAC003E HBAC004E HBAC005E HBAC006E HBAC007E HBAC008E HBAC009E HBAC010E HBAC011E HBAC012E	INCLIX™ HbA1c Control	INCLIX™ HbA1c control is intended to be used for in vitro diagnostic use in the quality control of INCLIX HbA1c assay kit. For in vitro diagnostic use.	12 50 01 06 00	Specific Protein Controls	other IVD/Annex III	2019-07-17	30.08.2019 Notification of Change: 06.12.2019
SUG-15-03	150731 Notification of Change (add new prod.):151958	IGEC001E IGEC002E IGEC003E IGEC004E IGEC005E IGEC006E IGEC007E IGEC008E IGEC009E IGEC010E IGEC011E IGEC012E	INCLIX™ Total IgE Control	INCLIX™ Total IgE control is intended to be used for in vitro diagnostic use in the quality control of INCLIX Total IgE assay kit. For in vitro diagnostic use.	12 50 01 06 00	Specific Protein Controls	other IVD/Annex III	2019-08-20	30.08.2019 Notification of Change: 06.12.2019
SUG-15-04	151958	IFNC001E	SGT i-flex Influenza Control	SGT i-flex Influenza control is intended to be used for in vitro diagnostic use in the quality control of SGT i-flex Influenza A&B assay kit. For in vitro diagnostic use.	12 50 01 06 00	Specific Protein Controls	other IVD/Annex III	2019-11-20	2019-12-06

Internal Adm.-No.AR	Registration Number German CA: DE/CA70/40838...	Cataloge No.	Product name (Model name)	Indications (Intended use)	EDMA-Code [GMDN-Code]	EDMA-Description (Product category)	Applied Annex	Declaration of Conformity Date	CE-Mark (Notification at CA)
SUG-16	151366	TSHT010E TSHT020E TSHT025E TSHT030E TSHT050E TSHT100E	INCLIX™ TSH	INCLIX™ TSH along with INCLIX™ analyzer is an immunoassay for quantitative determination of TSH in serum or plasma. The test is used as an aid in the diagnosis of TSH-mediated hyperthyroidism or hypothyroidism.	12 04 01 11 00	Thyroid Stimulating Hormone	other IVD/Annex III	2019-09-25	2019-10-16
SUG-17	151367 Notification of Change (add new prod.): 151955	TSHC001E TSHC002E TSHC003E TSHC004E TSHC005E TSHC006E TSHC007E TSHC008E TSHC009E TSHC010E TSHC011E	INCLIX™ TSH Control	INCLIX™ TSH control is intended to be used for in vitro diagnostic use in the quality control of INCLIX TSH assay kit. For in vitro diagnostic use.	12 50 01 04 00	Hormone Controls	other IVD/Annex III	2019-09-25	16.10.2019 Notification of Change: 05.12.2019
SUG-17-01	151955	BCGC001E BCGC002E BCGC003E BCGC004E BCGC005E BCGC006E BCGC007E BCGC008E BCGC009E BCGC010E BCGC011E BCGC012E	INCLIX™ βhCG Control	INCLIX™ βhCG control is intended to be used for in vitro diagnostic use in the quality control of INCLIX βhCG assay kit. For in vitro diagnostic use.	12 50 01 04 00	Hormone Controls	other IVD/Annex III	2019-10-15	2019-12-05
SUG-18	151956	TPIC001E TPIC002E TPIC003E TPIC004E TPIC005E TPIC006E TPIC007E TPIC008E TPIC009E TPIC010E TPIC011E	INCLIX™ Troponin I Control	INCLIX™ Troponin I control is intended to be used for in vitro diagnostic use in the quality control of INCLIX Troponin I assay kit. For in vitro diagnostic use.	12 50 01 08 00	Cardiac Marker Controls	other IVD/Annex III	2019-11-28	2019-12-05

Internal Adm.-No.AR	Registration Number German CA: DE/CA70/40838...	Cataloge No.	Product name (Model name)	Indications (Intended use)	EDMA-Code [GMDN-Code]	EDMA-Description (Product category)	Applied Annex	Declaration of Conformity Date	CE-Mark (Notification at CA)
SUG-19	153970 Notification of change (change intended use): 156486 Notification of change (add prod): 157915 Notification of change (add prod): 158845 Notification of change (delete prod.):	COMT010E, COMT020E, COMT025E, COMT030E, COMT050E, COMT100E	SGTi-flex COVID-19 IgM	SGTi-flex COVID-19 IgM Test is an immunoassay for qualitative detection of IgM antibodies to Covid-19 in human Serum/Plasma. The test is useful as a screening test for COVID-19 viral infection.	15 70 90 90 00	Other Other Virology Rapid Tests	General IVD	2020-03-09	12.03.2020 Notification of change: 30.06.2020 Notification of change: 08.09.2020 Notification of change: 22.10.2020 Notification of change: 28.10.2020
SUG-19-01	153970 Notification of change (change intended use): 156486 Notification of change (add prod): 157915 Notification of change (add prod): 158845 Notification of change (delete prod.):	COGT005E, COGT010E, COGT020E, COGT025E, COGT030E, COGT050E, COGT100E	SGTi-flex COVID-19 IgG	SGTi-flex COVID-19 IgG Test is an immunoassay for qualitative detection of IgG antibodies to Covid-19 in human whole blood, serum or plasma. The test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.	15 70 90 90 00	Other Other Virology Rapid Tests	General IVD	09.03.2020 revised: 25.06.2020 Revised: 19.08.2020	12.03.2020 Notification of change: 30.06.2020 Notification of change: 08.09.2020 Notification of change: 22.10.2020 Notification of change:
SUG-19-02	153970 Notification of change (change intended use): 156486 Notification of change (add prod): 157915 Notification of change (add prod): 158845 Notification of change (delete prod.): 158921	COVT005E, COVT010E, COVT020E, COVT025E, COVT030E, COVT050E, COVT100E	SGTi-flex COVID-19 IgM/IgG	SGTi-flex COVID-19 IgM/IgG Test is an immunoassay for qualitative detection of IgM or IgG antibodies to COVID-19 in human whole blood, serum or plasma. The test is useful as a screening test for COVID-19.	15 70 90 90 00	Other Other Virology Rapid Tests	General IVD	12.03.2020 Revised: 05.08.2020	12.03.2020 Notification of change: 30.06.2020 Notification of change: 08.09.2020 Notification of change: 22.10.2020 Notification of change: 28.10.2020
SUG-19-03	157915 Notification of change (add prod): 158845 Notification of change (delete prod.): 158921	CAGT010E0, CAGT020E0, CAGT025E0, CAGT010E1, CAGT020E1, CAGT025E1, CAGT010E2, CAGT020E2, CAGT025E2	SGTi-flex COVID-19 Ag	SGTi-flex COVID-19 Ag is an immunoassay for qualitative detection of SARS-CoV-2 antigens directly from nasopharyngeal and oropharyngeal swab specimens. The test is used as an aid in the rapid diagnosis of SARS-CoV-2 viral infections.	15 70 90 90 00	Other Other Virology Rapid Tests	General IVD	2020-08-21	08.09.2020 Notification of change: 22.10.2020 Notification of change: 28.10.2020

Internal Adm.-No.AR	Registration Number German CA: DE/CA70/40838...	Cataloge No.	Product name (Model name)	Indications (Intended use)	EDMA-Code [GMDN-Code]	EDMA-Description (Product category)	Applied Annex	Declaration of Conformity Date	CE-Mark (Notification at CA)
SUG-20	158846	ALIB024E	SGTi-Allergy Screen Inhalant Panel	SGTi-Allergy Screen Inhalant Panel is an immunoblotting method in vitro diagnostic medical device for semi-quantitative determination of allergenspecific immunoglobulin E for inhalation in human serum or plasma (Li-Heparin, Na-Citrate).	12 02 01 06 00	Immunoglobulin E- Screen	General IVD	2020-08-24	2020-10-22
SUG-20-01	158846	ALFB024E	SGTi-Allergy Screen Food Panel	SGTi-Allergy Screen Food Panel is an immunoblotting method in vitro diagnostic medical device for semiquantitative determination of allergen-specific immunoglobulin E for food in human serum or plasma (Li-Heparin, Na-Citrate).	12 02 01 06 00	Immunoglobulin E- Screen	General IVD	2020-08-24	2020-10-22
SUG-20-02	158846	ALCB048E	SGTi-Allergy Screen Combined	SGTi-Allergy Screen Combined is an immunoblotting method in vitro diagnostic medical device for semiquantitative determination of allergen-specific immunoglobulin E for inhalation and food in human serum or plasma (Li-Heparin, Na-Citrate).	12 02 01 06 00	Immunoglobulin E- Screen	General IVD	2020-08-24	2020-10-22
SUG-21	158922	COVE001E, COVE002E, COVE003E, COVE005E	SGT ANTI-SARS-COV-2 TOTAL AB ELISA	SGT Anti-SARS-CoV-2 Total Ab ELISA is an Enzyme-Linked Immunosorbent Assay (ELISA) intended for the qualitative detection of total antibodies (IgM/IgA/IgG) to SARS-CoV-2 in human serum and plasma. The test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or	15 04 90 90 00	Other Other Virology Reagents	General IVD	2020-09-04	2020-10-28

Remarks:

- All product, model or trade names haveto be specified
- Please specify the intended use

Internal Adm.-No.AR	Registration Number German CA: DE/CA70/40838...	Cataloge No.	Product name (Model name)	Indications (Intended use)	EDMA-Code [GMDN-Code]	EDMA- Description (Product category)	Applied Annex	Declaration of Conformity Date	CE-Mark (Notification at CA)
------------------------	---	--------------	------------------------------	----------------------------	--------------------------	---	------------------	---	------------------------------------

Prepared: MT Promedt Consulting GmbH

Released: Sugentech, Inc.

Internal Adm.-No.AR	Registration Number German CA: DE/CA70/40838...	Cataloge No.	Product name (Model name)	Indications (Intended use)	EDMA-Code [GMDN-Code]	EDMA- Description (Product category)	Applied Annex	Declaration of Conformity Date	CE-Mark (Notification at CA)
------------------------	---	--------------	------------------------------	----------------------------	--------------------------	---	------------------	---	------------------------------------

Internal Adm.-No.AR	Registration Number German CA: DE/CA70/40838...	Cataloge No.	Product name (Model name)	Indications (Intended use)	EDMA-Code [GMDN-Code]	EDMA- Description (Product category)	Applied Annex	Declaration of Conformity Date	CE-Mark (Notification at CA)
------------------------	---	--------------	------------------------------	----------------------------	--------------------------	---	------------------	---	------------------------------------

Supplemental Information

Product covered by Technical Documentation (Title, Revision, Date):

Technical File_INCLIX CRP, Rev.02, 2018-06-12 (TF-CRPT-00)

Technical File_INCLIX hsCR, Rev. 01, 2018-06-12 (TF-HCRT-00)

Technical File_INCLIX™ dual CRP, Rev.00, 2018-06-12 (TF-DCRT-00)

Technical File_INCLIX PCT, Rev.02, 2018-06-12 (TF-PCTT-00)

Technical File_INCLIX, 2016-08-05 (SGT-TCF-03)

Product covered by Technical Documentation (Title, Revision, Date):

TDP-KRF-01, Rev. 01, 2019-04-30

TF-HCG-04, Rev. 04, 2018-05-18

TF-HCGM-02, Rev. 02, 2018-05-18

TF-HLH-04, Rev. 04, 2018-05-18

TF-HCG-04, Rev. 04, 2018-05-18

Product covered by Technical Documentation (Title, Revision, Date):

TF-HCGI-02, Rev. 02, 2018-05-18

TF-HCGI-02, Rev. 02, 2018-05-18

TF-HCGM-02, Rev. 02, 2018-05-18

TF-HLH-04, Rev. 04, 2018-05-18

TF-HBAT-00, Rev.01, 2018-06-12

Product covered by Technical Documentation (Title, Revision, Date):

TF-TPIT-00, Rev.02, 2019-11-28

TF-CT05-00, Rev.01, 2018-06-12

TF-CO10-00/ Rev.00/2020-03-26

TF-IFNT00, Rev.01, 2018-06-12

TF-ZIKT-01, Rev.01, 2018-06-12

Product covered by Technical Documentation (Title, Revision, Date):

TF-ZIAT-00, Rev. 00, 2019-03-25

TF-BCGT-00 Rev.02, 2019-10-15

TF-IGET-01, Rev.01, 2018-06-12

TF-TBCT-00, Rev. 00, 2019-01-25

TF-PCTT-03, Rev. 03, 17.07.2019

Product covered by Technical Documentation (Title, Revision, Date):

TF-CRPT-03, Rev.03, Date 17.07.2019

TF-HBAT-03, Rev.03, Date 17.07.2019

TF-IGET-02, Rev.02, Date 20.08.2019

TF-IFNT-02 ,Rev.02,2019-11-20

Product covered by Technical Documentation (Title, Revision, Date):

TF-TSHT-00, Rev.00, Date 25.09.2019

TF-TSHT-00, Rev.00, Date 25.09.2019

TF-BCGT-00 Rev.02, 2019-10-15

TF-TPIT-00, Rev.02, 2019-11-28

Product covered by Technical Documentation (Title, Revision, Date):

TF-COMT-00 / Rev.00 / 2020-03-06

TF-COGT-00 / Rev.02 / 2020-08-19

TF-COVT-04/ Rev.04/2020-08-05

TF-CAGT-00/ Rev.00/2020-08-21

Product covered by Technical Documentation (Title, Revision, Date):

TF-ALEB-00, Rev.00, 2020-08-21

TF-COVE-00, Rev.00, 28.08.2020

Product covered by Technical Documentation (Title, Revision, Date):

Product covered by Technical Documentation (Title, Revision, Date):

Product covered by Technical Documentation (Title, Revision, Date):