



Certificate of CE-Registration

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

**Daan Gene Co., Ltd.
No. 19, Xiangshan Road, Science Park
High & New Technology Development District
510665 Guangzhou, Guangdong
CHINA**

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

Annex A dated 2022-04-12

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

2022-04-12

Dr. Philipp Hohenbrink
Director AR Services
MDSS GmbH

**Annex A: 2022-04-12
Manufacturer: DAAN GENE CO., LTD.**

REF	Device Names (notified)	Nomenclature	Code (notified)	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
DR-CM-A006	Quantitative Diagnostic Kit for Carbohydrate Antigen CA15-3 (TRFIA)	EDMA	12 03 01 02 00	Cancer Antigen 15-3	"Other"	N/A	DE/CA09/0170/D01/JVD/011-01
DR-CM-A004	Quantitative Diagnostic Kit for Tumor Marker CA 19-9 (TRFIA)	EDMA	12 03 01 03 00	Cancer Antigen 19-9	"Other"	N/A	DE/CA09/0170/D01/JVD/010-01
DR-CM-A007	Quantitative Diagnostic Kit for CA50 (TRFIA)	EDMA	12 03 01 04 00	Cancer Antigen 50	"Other"	N/A	DE/CA09/0170/D01/JVD/006-02
DR-CM-A003	Quantitative Diagnostic Kit for Tumor Marker CA 125 (Fluoroimmunoassay)	EDMA	12 03 01 06 00	Cancer Antigen 125	"Other"	N/A	DE/CA09/0170/D01/JVD/007-01
DA-077	Fusion Gene BCR-ABL Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	12 03 90 90 00	Other Other Tumour Markers	"Other"	N/A	DE/CA09/0170/D01/JVD/019-01
DA-076	Multidrug Resistance Gene MDR1 Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	12 03 90 90 00	Other Other Tumour Markers	"Other"	N/A	DE/CA09/0170/D01/JVD/019-01
DA-054-1	Chlamydia trachomatis Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 01 01 40 00	Chlamydia Detection by NA Reagents	Annex II - List B	0344 / 2113304CE01 Expiry 2024-05-26	DE/CA09/0170/D01/JVD/031-02
DA-066-1	Chlamydia pneumoniae Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 01 01 40 00	Chlamydia Detection by NA Reagents	Annex II - List B	0344 / 2113304CE01 Expiry 2024-05-26	DE/CA09/0170/D01/JVD/031-02
DA0060; DA0061; DA0062; DA0063	Diagnostic Kit for Quantification of Neisseria Gonorrhoeae (PCR-Fluorescence Probing)	EDMA	15 01 02 40	Gonococcal detection by NA Reagents	"Other"	N/A	DE/CA09/0170/D01/JVD/043
DA-062-1	Treponema pallidum Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 01 03 40 00	Syphilis detection by NA Reagents	"Other"	N/A	DE/CA09/0170/D01/JVD/024-01
DA-063-1	Helicobacter pylori Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 01 04 40 00	H. Pylori Detection by NA Reagents	"Other"	N/A	DE/CA09/0170/D01/JVD/021-02

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DA-069-1	Legionella Pneumophila Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 01 05 40 00	Legionella Detection by NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/020-01
DA-052	Mycobacterium tuberculosis Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 01 07 40	Mycobacteria Detection by NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/026-03
DA0050; DA0051; DA0052	Diagnostic Kit for Mycobacterium Tuberculosis DNA (PCR-Fluorescence)	EDMA	15 01 07 40	Mycobacteria Detection by NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/026-03
DA1240; DA1241; DA1242	Detection Kit for Mycobacterium Tuberculosis Complex Nucleic Acid (PCR-Fluorescence Probing)	EDMA	15 01 07 40	Mycobacteria Detection by NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/026-03
DA-064-1	Mycoplasma Pneumonia Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 01 08 40	Mycoplasma Detection by NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/028-02
DA-055-1	Ureaplasma urealyticum Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 01 08 40	Mycoplasma Detection by NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/028-02
DA0080; DA0081; DA0082; DA0083	Diagnostic Kit for Ureaplasma Urealyticum DNA (PCR-Fluorescence Probing)	EDMA	15 01 08 40	Mycoplasma Detection by NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/028-02
DA-102	Salmonella Polymerase Chain Reaction Diagnostic Kit	EDMA	15 01 10 40 00	Salmonella Detection by NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/009-03
DA-121	Salmonella Typhi Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 01 10 40 00	Salmonella Detection by NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/009-03
DA-081	Streptococcus pneumoniae Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 01 11 40 00	Streptococcal Detection by NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/004-01
DA-105	Campylobacter jejuni Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 01 14 40 00	Campylobacter Detection by NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/003-01
DA-083	Enterohemorrhagic Escherichia coli O157 Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 01 15 40 00	E. coli Detection by NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/005-01
DA-136	Brucella Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 01 40 01 00	Brucella - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/013-01
DA-464	Neisseria meningitidis Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 01 40 11	Neisseria meningitidis - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/032-01
DA-107	Shigella spp. Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 01 40 14 00	Shigella - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/002-01

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DA-053-1	Neisseria gonorrhoeae Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 01 40 90 00	Other Other Bacteriology - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/023-02
DA-133	Vibrio cholerae Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 01 40 90 00	Other Other Bacteriology - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/023-02
DA-061-1	Human Cytomegalovirus Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 02 40 00	CMV- NA Reagents	Annex II - List B	0344 / 2113304CE01 Expiry 2024-05-26	DE/CA09/0170/D01/IVD/030-02
DA-059	Herpes Simplex Virus II Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 03 40 00	HSV - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/029-01
DA-091	Herpes Simplex Virus I Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 03 40 00	HSV - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/029-01
DA-065	Epstein Barr Virus Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 04 40	EBV - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/027-03
DA0150; DA0151; DA0153	Epstein-Barr Virus (EBV) Polymerase Chain Reaction (PCR) Fluorescence Quantitative Diagnostic Kit	EDMA	15 04 04 40	EBV - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/027-03
DA1250; DA1251; DA1252	Detection Kit for Epstein-Barr Virus Nucleic Acid (PCR-Fluorescence Probing)	EDMA	15 04 04 40	EBV - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/027-03
DA-238	Measles Virus Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 05 40	Measles - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/033-01
DA-220	Varicella-zoster Virus Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 07 40	Varicella Zoster - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/001-01
DA-240	Middle East Respiratory Syndrome Coronavirus Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 09 40	Coronavirus - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/036-01
DA0990; DA0991; DA0992; DA0993; DA0994; DA0995	Detection Kit for 2019-nCoV (PCR-Fluorescence)	EDMA	15 04 09 40	Coronavirus - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/039-02



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DA1060; DA1061	Detection Kit for SARS-CoV-2 UK and South African Variants (PCR-Fluorescence)	EDMA	15 04 09 40	Coronavirus, NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/041-03
DA1070; DA1071; DA1072; DA1073; DA1074; DA1075; DA1076;	Detection Kit for 2019-nCoV (PCR-Fluorescence)	EDMA	15 04 09 40	Coronavirus, NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/041-03
DA1077; DA1160; DA1161	2019-nCoV Delta Variant Detection Kit (PCR-Fluorescence Probing)	EDMA	15 04 09 40	Coronavirus - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/041-03
DA1170; DA1171	Detection Kit for 2019-nCoV (N/E/RDRP Gene)	EDMA	15 04 09 40	Coronavirus - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/041-03
DA1220; DA1221	2019-nCoV Omicron Variant Detection Kit (PCR-Fluorescence)	EDMA	15 04 09 40	Coronavirus - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/041-03
DA-067-1	Adenovirus Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 40 01 00	Adenovirus - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/022-01
DA-109	Enterovirus Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 40 02 00	Enterovirus - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/015-04
DA-110	Coxsackievirus A16 Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 40 02 00	Enterovirus - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/015-04
DA-108	Enterovirus 71 Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 40 02 00	Enterovirus - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/015-04
DA-482	Coxsackievirus A6 Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 40 02 00	Enterovirus - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/015-04
DA0570; DA0571; DA0572	Diagnostic Kit for Coxsackievirus A6 RNA (PCR-Fluorescence Probing)	EDMA	15 04 40 02 00	Enterovirus - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/015-04

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DA0320; DA0321; DA0322	Detection Kit for Enterovirus 71/Coxsackievirus A16/Enterovirus RNA (PCR-Fluorescence Probing)	EDMA	15 04 40 02 00	Enterovirus - NA Reagents	"Other"	N/A	DE/CA09/0170/D001/JVD/015-04
DA-056-1	Human Papillomavirus Types 6 and 11 Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 08 43	Other HPV - NA Reagents	"Other"	N/A	DE/CA09/0170/D001/JVD/025-03
DA-057-1	Human Papillomavirus Types 16 and 18 Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 08 43	Other HPV - NA Reagents	"Other"	N/A	DE/CA09/0170/D001/JVD/025-03
DA-092	High-risk Human Papillomavirus Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 08 43	Other HPV - NA Reagents	"Other"	N/A	DE/CA09/0170/D001/JVD/025-03
DA1180; DA1181	Human Papilloma Virus (HPV) Detection Kit (PCR-Fluorescence Probing)	EDMA	15 04 08 43	Other HPV - NA Reagents	"Other"	N/A	DE/CA09/0170/D001/JVD/025-03
DA0540	HPV (16/18 genotypes) DNA TEST (Real-Time PCR)	EDMA	15 04 08 43	Other HPV - NA Reagents	"Other"	N/A	DE/CA09/0170/D001/JVD/025-03
DA-094	Influenza A Virus Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 40 04 00	Influenza & Para Influenza - NA Reagents	"Other"	N/A	DE/CA09/0170/D001/JVD/018-04
DA-095	Influenza B Virus Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 40 04 00	Influenza & Para Influenza - NA Reagents	"Other"	N/A	DE/CA09/0170/D001/JVD/018-04
DA-143	Human Influenza Virus Subtype H1 Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 40 04 00	Influenza & Para Influenza - NA Reagents	"Other"	N/A	DE/CA09/0170/D001/JVD/018-04
DA-144	Human Influenza Virus Subtype H3 Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 40 04 00	Influenza & Para Influenza - NA Reagents	"Other"	N/A	DE/CA09/0170/D001/JVD/018-04
DA-093	Influenza A H1N1 Virus (2009) Fluorescent Polymerase Chain Diagnostic Kit	EDMA	15 04 40 04 00	Influenza & Para Influenza - NA Reagents	"Other"	N/A	DE/CA09/0170/D001/JVD/018-04
DA-086	Respiratory Syncytial Virus Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 40 05 00	Respiratory Syncytial Virus (RSV) - NA Reagents	"Other"	N/A	DE/CA09/0170/D001/JVD/017-02
DA0200; DA0201; DA0202; DA0203	Detection Kit for Respiratory Syncytial Virus RNA (PCR-Fluorescence Probing)	EDMA	15 04 40 05 00	Respiratory Syncytial Virus (RSV) - NA Reagents	"Other"	N/A	DE/CA09/0170/D001/JVD/017-02
DA-104	Group A of Rotavirus Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 40 06 00	Rotavirus - NA Reagents	"Other"	N/A	DE/CA09/0170/D001/JVD/034-01

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DA-100	Human Parvovirus B19 Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 40 09 00	Parvovirus B 19 - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/014-01
DA-156	Dengue Virus Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 40 11 00	Dengue Virus - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/012-01
DA-078	Severe Fever with Thrombocytopenia Syndrome Bunyavirus Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 40 14 00	Hantavirus / Bunyavirus - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/008-02
DA-472	Avian Influenza Virus H7N9 Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 40 15	Avian Influenza - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/035-01
DA-096	Norwalk Virus Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 40 90 00	Other Virology - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/016-04
DA-090	Rabies Virus Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 40 90 00	Other Virology - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/016-04
DA-106	Human Bocavirus Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 40 90 00	Other Virology - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/016-04
DA-082	Japanese Encephalitis Virus Fluorescent Polymerase Chain Reaction Diagnostic Kit	EDMA	15 04 40 90 00	Other Virology - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/016-04
DA-930	Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA (PCR-Fluorescence Probing)	EDMA	15 04 40 90 00	Other Virology - NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/016-04
DA1040; DA1041; DA1042	Detection Kit for Influenza A/B and 2019-nCoV (PCR-Fluorescence Probing)	EDMA	15 30 02 42	Influenza & Para Influenza / Respiratory Syncytial Virus (RSV) / SARS-CoV - Multiplex NA Reagents	"Other"	N/A	DE/CA09/0170/D01/IVD/040-01
DA0633	RNA/DNA Purification Kit (Magnetic Bead)	EDMA	15 90 40 01	Reagents for DNA and/or RNA extraction and preparation bacteria and/or virus	"Other"	N/A	DE/CA09/0170/D01/IVD/038-05
DA0591	RNA/DNA Purification Kit (Spin Column)	EDMA	15 90 40 01	Reagents for DNA and/or RNA extraction and preparation bacteria and/or virus	"Other"	N/A	DE/CA09/0170/D01/IVD/038-05

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DA0940	RNA/DNA Purification Kit (Preservation)	EDMA	15 90 40 01	Reagents for DNA and/or RNA extraction and preparation bacteria and/or virus	"Other"	N/A	DE/CA09/0170/D01/IVD/038-05
DA0950	RNA/DNA Purification Kit (Release)	EDMA	15 90 40 01	Reagents for DNA and/or RNA extraction and preparation bacteria and/or virus	"Other"	N/A	DE/CA09/0170/D01/IVD/038-05
DA0960	RNA/DNA Purification Kit (Preservation/Release)	EDMA	15 90 40 01	Reagents for DNA and/or RNA extraction and preparation bacteria and/or virus	"Other"	N/A	DE/CA09/0170/D01/IVD/038-05
DA0970	Specimen Preservation Reagent	EDMA	15 90 40 01	Reagents for DNA and/or RNA extraction and preparation bacteria and/or virus	"Other"	N/A	DE/CA09/0170/D01/IVD/038-05
DA0980	Specimen Preservation Solution	EDMA	15 90 40 01	Reagents for DNA and/or RNA extraction and preparation bacteria and/or virus	"Other"	N/A	DE/CA09/0170/D01/IVD/038-05
DA0621	Nucleic Acid Isolation or Purification Reagent	EDMA	15 90 40 01	Reagents for DNA and/or RNA extraction and preparation bacteria and/or virus	"Other"	N/A	DE/CA09/0170/D01/IVD/038-05
DA0623							
DA0626							
DA0600;	Nucleic Acid Extraction Kit						
DA0601;							
DA0602;							
DA0603;							
DA0604;							
DA1000;							
DA1001;							
DA1002;							
DA1003;							
DA1004							
DA0890;	CYP2C19 Genotyping Detection Kit (PCR-Fluorescence Probing)	EDMA	16 30 01 03	CYP2C19	"Other"	N/A	DE/CA09/0170/D01/IVD/042
DA0891							
DA8050	Sample Processing System (Model: Stream DP96)	EDMA	28 01 10 01	SP Hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/D01/IVD/045

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DA8030	Nucleic Acid Extraction Instrument (Model: Smart32)	GMDN	60736	Nucleic acid sample preparation instrument IVD, automated	"Other"	N/A	DE/CA09/0170/D01/IVD/044-02
DA8044	Automatic Nucleic Acid Extraction Instrument (Model: Stream SP96)	GMDN	60736	Nucleic acid sample preparation instrument IVD, automated	"Other"	N/A	DE/CA09/0170/D01/IVD/044-02
DA8045	Automatic Nucleic Acid Extraction Instrument (Model: Swift96)	EDMA	60736	Nucleic acid sample preparation instrument IVD, automated	"Other"	N/A	DE/CA09/0170/D01/IVD/044-02