

Demeditec Diagnostics GmbH
Lise-Meitner-Str. 2
24145 Kiel
Germany

hereby declares under its own responsibility that the in vitro diagnostic medical device

name of product: Annex I

- is classified as a "all other IVD Medical Devices" according to Annex II of the EC Council Directive 98/79/EC from 27th October 1998 on in-vitro diagnostic medical devices
- is in accordance with the Annex III (except of chapter 6) of the EC Council Directive 98/79/EC from 27th October 1998 on in-vitro diagnostic medical devices
- conform to the relevant provisions of the EC Council Directive 98/79/EC from 27th October 1998

erklärt hiermit, in alleiniger Verantwortung, dass das In vitro Diagnostikum

Produktbezeichnung: Annex I

- gemäß Anhang II der EG-Richtlinie 98/79/EG vom 27. Oktober 1998 über in-vitro Diagnostika als "Sonstiges In-vitro-Diagnostikum" klassifiziert ist
- den Verpflichtungen des Anhang III (ausgenommen Kapitel 6) der EG-Richtlinie 98/79/EG vom 27. Oktober 1998 nachkommt
- allen übrigen relevanten Verpflichtungen der EG-Richtlinie 98/79/EG vom 27. Oktober 1998 genügt

Harmonized standards applied:

Angewandte harmonisierte Normen:

DIN EN ISO 9001:2015-11	DIN EN ISO 13485:2016	DIN EN ISO 13612:2002
DIN EN ISO 13975: 2003	DIN EN ISO 14971:2020-07	DIN EN ISO 15223-1:2017-04
DIN EN ISO 23640:2015-12	DIN EN ISO 18113-1:2013-01	DIN EN ISO 18113-2:2013-01

Demeditec has a Quality System in place based on EN ISO 9001:2015 and EN ISO 13485:2016, issued by mdc medical device certification GmbH.

Demeditec ist zertifiziert nach EN ISO 9001:2015 und EN ISO 13485:2016 durch mdc medical device certification GmbH.

Valid until / gültig bis: 25.05.2026

Kiel-Wellsee, 03.05.2022



Claudia Banasch
- Regulatory Affairs -



Dr. Arndt Stüber
- General Manager -

Annex I

Declaration of Conformity according to European Directive of in vitro diagnostic medical devices (98/79/EG) of the Medical Devices Act (MPG).

Product	Cat.-No. Demeditec	Methode	Conformity
17-OH-Progesterone	DEH3322	ELISA	CE
17-OH-Progesterone free in Saliva	DESLV3140	ELISA	CE
25-OH Vitamin D total	DE1971	ELISA	CE
25-OH Vitamin D total	DER1971	RIA	CE
2-CAT	DEE6500	ELISA	CE
3-CAT	DEE6600	ELISA	CE
5-HIAA	DEE1900	ELISA	CE
Active-B12 (Holotranscobalamin)	DEFMABT100	ELISA	CE
Adiponectin human	DEE009	ELISA	CE
Aldosterone	DE5298	ELISA	CE
Aldosterone	DERCW100	RIA	CE
AMA-M2	DE7000	ELISA	CE
AMH	DE6141	ELISA	CE
ANA Hep Screen	DE7020	ELISA	CE
ANA Profile	DE7010	ELISA	CE
ANA Screen	DE7030	ELISA	CE
ANCA Profile	DE7040	ELISA	CE
ANCA Screen	DE7050	ELISA	CE
ANCA-C (PR3)	DE7060	ELISA	CE
ANCA-P (MPO)	DE7080	ELISA	CE
Androstenedione	DE3265	ELISA	CE
Androstenedione free in Saliva	DESLV4780	ELISA	CE
Annexin V Ab IgG/IgM	DE7100	ELISA	CE
Anti-Ovarian Ab	DE2937	ELISA	CE
Anti-Spermatozoa Antibody (ASA) seminal	DE1021	ELISA	CE
Anti-Spermatozoa Antibody (ASA) serum	DE1020	ELISA	CE
ASCA IgG/IgA	DE7240	ELISA	CE
Ascaris lumbricoides IgG	DEASCG0020	ELISA	CE
Aspergillus fumigatus IgG	DEASPG0680	ELISA	CE
Aspergillus fumigatus IgM	DEASPM0680	ELISA	CE
beta2-Glycoprotein I Ab IgA	DE7250	ELISA	CE
beta2-Glycoprotein I Ab IgG/IgM	DE7260	ELISA	CE
beta2-Glycoprotein I Screen	DE7270	ELISA	CE
beta-2-Microglobulin	DE7610	ELISA	CE
Bordetella pertussis IgG	DEBOPG0030	ELISA	CE
Bordetella pertussis IgM	DEBOPM0030	ELISA	CE
Borrelia burgdorferi IgG	DEBORG0040	ELISA	CE
Borrelia burgdorferi IgM	DEBORM0040	ELISA	CE
Brucella IgG	DEBRUG0050	ELISA	CE
Brucella IgM	DEBRUM0050	ELISA	CE
C1q Ab	DE7280	ELISA	CE
CA125	DE5072	ELISA	CE

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CA15-3	DE5068	ELISA	CE
CA19-9	DE5069	ELISA	CE
CA72-4	DE5071	ELISA	CE
CA72-4	DE51100	IRMA	CE
Calcitonin	DE16100	IRMA	CE
Calcitonin ultra sensitive	DEKAP0421	ELISA	CE
Calprotectin	DE843	Sample Collection Kit	CE
Calprotectin	DE849		CE
Candida albicans IgG	DECANG0060	ELISA	CE
Candida albicans IgM	DECANM0060	ELISA	CE
Cardiolipin Ab IgA	DE7290	ELISA	CE
Cardiolipin Ab IgG/IgM	DE7300	ELISA	CE
Cardiolipin Screen	DE7310	ELISA	CE
CCP Ab	DE7760	ELISA	CE
CEA	DE1868	ELISA	CE
CEA	DE38100	IRMA	CE
Chagas (Trypanosoma cruzi) IgG	DENO0114	ELISA	CE
Chromogranin A	DEE9000	ELISA	CE
Clostridium tetani toxin IgG	DETETG0430	ELISA	CE
Corticosterone	DE4164	ELISA	CE
Cortisol	DE28100	RIA	CE
Cortisol	DEH3388	ELISA	CE
Cortisol free in Saliva	DES6611	ELISA	CE
Cortisol in urine	DE2989	ELISA	CE
Corynebacterium diphtheriae toxin IgG	DECORG0090	ELISA	CE
COVID-19 (SARS-CoV-2) quantitative IgG	DECOV1901Q	ELISA	CE
C-Peptide	DE1293	ELISA	CE
CRP	DE740001	ELISA	CE
CYFRA 21-1	DE5070	ELISA	CE
Dengue Virus IgG	DENG0120	ELISA	CE
Dengue Virus IgM	DENM0120	ELISA	CE
DGP Ab IgA	DE7770	ELISA	CE
DGP Ab IgG	DE7780	ELISA	CE
DHEA	DEH3344	ELISA	CE
DHEA free in Saliva	DES6666	ELISA	CE
DHEA-S	DE1562	ELISA	CE
Dihydrotestosterone (DHT)	DE5761	ELISA	CE
Dopamine	DEE6300	ELISA	CE
ds-DNA Ab IgG	DE7360	ELISA	CE
ds-DNA Screen	DE7370	ELISA	CE
Echinococcus IgG	DEECHG0130	ELISA	CE
ENA Combi	DE7390	ELISA	CE

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Product	Cat.-No. Demeditec	Methode	Conformity
ENA Screen	DE7420	ELISA	CE
ENA-6 Profile	DE7410	ELISA	CE
Entamoeba histolytica IgG	DEENTG0140	ELISA	CE
EPO (Erythropoietin)	DE3646	ELISA	CE
Epstein-Barr Virus (EBNA-1) IgG	DE4246	ELISA	CE
Epstein-Barr Virus (EBNA-1) IgM	DE4247	ELISA	CE
Epstein-Barr Virus (VCA) IgA	DEEBVA0150	ELISA	CE
Epstein-Barr Virus (VCA) IgG	DEEBVG0150	ELISA	CE
Epstein-Barr Virus (VCA) IgM	DEEBVM0150	ELISA	CE
Estradiol	DE2693	ELISA	CE
Estradiol free in Saliva HS	DESLV6145	ELISA	CE
Estradiol sensitive	DE4399	ELISA	CE
Estriol unconjugated	DE1612	ELISA	CE
Estrone	DE4174	ELISA	CE
Ferritin	DE34100	IRMA	CE
Ferritin	DE4408	ELISA	CE
FSH	DE1288	ELISA	CE
GBM Ab	DE7130	ELISA	CE
Giardia lamblia	DE610001	ELISA	CE
hCG	DE1469	ELISA	CE
Herpes simplex Virus 1 (HSV 1) IgG	DEHSV1G0500	ELISA	CE
Herpes simplex Virus 1 (HSV 1) IgM	DEHSV1M0500	ELISA	CE
Herpes simplex Virus 1+2 (HSV) IgG	DEHSV0250	ELISA	CE
Herpes simplex Virus 1+2 (HSV) IgM	DEHSVM0250	ELISA	CE
Herpes simplex Virus 2 (HSV 2) IgG	DEHSV2G0540	ELISA	CE
Herpes simplex Virus 2 (HSV 2) IgM	DEHSV2M0540	ELISA	CE
Histamine	DEE1000	ELISA	CE
hPL	DE1283	ELISA	CE
hsCRP	DE740011	ELISA	CE
IFN-gamma human	DE4434	ELISA	CE
IGFBP-3	DEE003A	ELISA	CE
IGF-I	DEE020	ELISA	CE
IGF-I 600	DE4140	ELISA	CE
IgG4 Screen Nutritional 20	DE40496	ELISA	CE
IgG4 Screen Nutritional 88	DE40188	ELISA	CE
Influenza Virus A IgG	DEINFG0290	ELISA	CE
Influenza Virus B IgG	DEINFG0300	ELISA	CE
Insulin	DE2935	ELISA	CE
Insulin	DE39100	IRMA	CE
Insulin Ab	DE7430	ELISA	CE
Interleukin-10 human	DE4699	ELISA	CE
Interleukin-1beta human	DE4437	ELISA	CE

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Interleukin-6 human	DE4640	ELISA	CE
Interleukin-8 human	DE4700	ELISA	CE
Intrinsic Factor Ab	DE7140	ELISA	CE
Jo-1 Ab	DE7440	ELISA	CE
Legionella pneumophila IgG	DELEGG0650	ELISA	CE
Legionella pneumophila IgM	DELEGM0650	ELISA	CE
Leishmania infantum IgG	DEIG0310	ELISA	CE
Leptin	DEE007	ELISA	CE
LH	DE1289	ELISA	CE
Measles Virus IgG	DEMEAG0330	ELISA	CE
Measles Virus IgM	DEMEAM0330	ELISA	CE
Metanephrine Plasma	DEE8100	ELISA	CE
Metanephrine Urine	DEE8400	ELISA	CE
Mumps Virus IgG	DEMUMG0340	ELISA	CE
Mumps Virus IgM	DEMUMM0340	ELISA	CE
Mycoplasma pneumoniae IgA	DEMYCA0350	ELISA	CE
Mycoplasma pneumoniae IgG	DEMYCG0350	ELISA	CE
Mycoplasma pneumoniae IgM	DEMYCM0350	ELISA	CE
Neopterin	DE59321	ELISA	CE
Nephrines Plasma	DEE8300	ELISA	CE
Nephrines Urine	DEE8600	ELISA	CE
Normetanephrine Plasma	DEE8200	ELISA	CE
Normetanephrine Urine	DEE8500	ELISA	CE
NSE	DE2353	ELISA	CE
Parietal Cell Ab	DE7450	ELISA	CE
Parvovirus B19 IgG	DE3503	ELISA	CE
Parvovirus B19 IgM	DE3504	ELISA	CE
Phosphatidyl Inositol Ab IgG/IgM	DE7200	ELISA	CE
Phospholipid Screen IgG/IgM	DE7470	ELISA	CE
Plasma Renin Activity (PRA)	DEMSE5600	ELISA	CE
PLGF (Placenta growth factor)	DE4529	ELISA	CE
PMN Elastase	DEH3311	ELISA	CE
Progesterone	DE1561	ELISA	CE
Progesterone free in Saliva HS	DESLV5911	ELISA	CE
Prolactin	DE1291	ELISA	CE
Protein C	DE10901	ELISA	CE
Protein S	DE10902	ELISA	CE
PTH intact	DE3645	ELISA	CE
Renin	DE5125	ELISA	CE
Respiratory Syncytial Virus IgG	DERSVG0380	ELISA	CE
Rheumatoid Factor IgA	DE7630	ELISA	CE
Rheumatoid Factor IgG	DE7640	ELISA	CE

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Rheumatoid Factor IgM	DE7650	ELISA	CE
Rheumatoid Factor Screen	DE7660	ELISA	CE
RNP 70 Ab	DE7490	ELISA	CE
RNP/Sm Ab	DE7500	ELISA	CE
Schistosoma mansoni IgG	DESCHG0410	ELISA	CE
Scl-70 Ab	DE7510	ELISA	CE
Serotonin	DEE8900	ELISA	CE
SHBG	DE2996	ELISA	CE
Sm Ab	DE7520	ELISA	CE
SS-A Ab	DE7550	ELISA	CE
SS-B Ab	DE7560	ELISA	CE
ss-DNA Ab	DE7570	ELISA	CE
Strongyloides IgG/IgM	DESTRO0690	ELISA	CE
T3 free	DE3801	ELISA	CE
T4 free	DE3775	ELISA	CE
Taenia solium IgG	DETAEG0420	ELISA	CE
TBE/FSME IgG	DETICG0440	ELISA	CE
TBE/FSME IgM	DETICM0440	ELISA	CE
Testosterone	DE1559	ELISA	CE
Testosterone free	DE2924	ELISA	CE
Testosterone free	DE4369	RIA	CE
Testosterone free in Saliva	DES6622	ELISA	CE
Thyroidal Peroxidase-Ab (TPO-Ab)	DE7580	ELISA	CE
Thyroglobulin (hTg)	DE20100	IRMA	CE
Thyroglobulin (hTg)	DE7680	ELISA	CE
Thyroglobulin-Ab (Tg-Ab)	DE7590	ELISA	CE
Tissue Transglutaminase Ab IgA	DE7720	ELISA	CE
Tissue Transglutaminase Ab IgG	DE7730	ELISA	CE
TNF-alpha human	DE4641	ELISA	CE
Total IgE	DEIGE02	ELISA	CE
Toxocara canis IgG	DE0450	ELISA	CE
Treponema pallidum (Syphilis) IgG	DE3517	ELISA	CE
Treponema pallidum (Syphilis) IgM	DE4267	ELISA	CE
Trichinella spiralis IgG	DETRIG0480	ELISA	CE
TSH	DE4171	ELISA	CE
Varicella-Zoster Virus (VZV) IgG	DEVZVG0490	ELISA	CE
Varicella-Zoster Virus (VZV) IgM	DEVZVM0490	ELISA	CE
*end of list			