

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

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

name of product: **listed at Annex I**

- are 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
- are 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
- are 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 Diagnostika

Produktbezeichnung: **gelistet in 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
DIN EN ISO 13975
DIN EN ISO 23640
DIN EN ISO 62366

DIN EN ISO 13485
DIN EN ISO 14971
DIN EN ISO 18113-1

DIN EN ISO 13612
DIN EN ISO 15223-1
DIN EN ISO 18113-2

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: 07.01.2021

Kiel-Wellsee, 06.02.2020



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.	Method
17-OH-Progesterone	DEH3322	ELISA
17-OH-Progesterone free in Saliva	DESLV3140	ELISA
25-OH Vitamin D total	DE1971	ELISA
25-OH Vitamin D total	DER1971	RIA
25-OH Vitamin D3	DEKIP1961	RIA
2-CAT	DEE6500	ELISA
3-CAT	DER6600	RIA
3-CAT	DEE6600	ELISA
5-HIAA	DEE1900	ELISA
ACPA	DE7170	ELISA
ACTH	DE3647	ELISA
Active-B12 (Holotranscobalamin)	DEFMABT100	ELISA
Adenovirus IgG	DEADV01	ELISA
Adenovirus IgM	DEADV03	ELISA
Adiponectin human	DEE009	ELISA
Adrenaline	DEE6100	ELISA
AFP	DE1468	ELISA
Aldosterone	DE5298	ELISA
Aldosterone	DERCW100	RIA
alpha-Amylase Saliva	DEEQ6231	ELISA
AMA-M2	DE7000	ELISA
ANA Hep Screen	DE7020	ELISA
ANA Profile	DE7010	ELISA
ANA Screen	DE7030	ELISA
ANCA Profile	DE7040	ELISA
ANCA Screen	DE7050	ELISA
ANCA-C (PR3)	DE7060	ELISA
ANCA-P (MPO)	DE7080	ELISA
Androstenedione	DE3265	ELISA
Androstenedione free in Saliva	DESLV4780	ELISA
Annexin V Ab IgG/IgM	DE7100	ELISA
Anti-GAD	DEGDE96	ELISA
Anti-IA2	DEIAE962	ELISA
Anti-LKM-1	DE7703	ELISA
Anti-R-TSH Ab	DETCT100	RIA
Anti-Spermatozoa Antibody (ASA) serum	DE1020	ELISA
ASCA IgG/IgA	DE7240	ELISA
Ascaris lumbricoides IgG	DEASCG0020	ELISA
Aspergillus fumigatus IgG	DEASP01	ELISA
Aspergillus fumigatus IgM	DEASP03	ELISA
beta2-Glycoprotein I Ab IgA	DE7250	ELISA
beta2-Glycoprotein I Ab IgG/IgM	DE7260	ELISA

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Product	Cat.-No.	Method
beta2-Glycoprotein I Screen	DE7270	ELISA
beta-2-Microglobulin	DE7610	ELISA
beta-hCG	DE1911	ELISA
Bordetella pertussis FHA IgA	DEBPT08	ELISA
Bordetella pertussis FHA IgG	DEBPT07	ELISA
Bordetella pertussis IgG	DEBPT01	ELISA
Bordetella pertussis IgM	DEBPT03	ELISA
Bordetella pertussis toxin IgG	DEBPT04	ELISA
Borrelia burgdorferi IgG	DEBOR01	ELISA
Borrelia burgdorferi IgM	DEBOR03	ELISA
Brucella abortus IgG	DEBRU01	ELISA
Brucella abortus IgM	DEBRU03	ELISA
C1q Ab	DE7280	ELISA
C5a	DE3327	ELISA
CA125	DE5072	ELISA
CA15-3	DE5068	ELISA
CA19-9	DE5069	ELISA
CA19-9	DE50100	IRMA
CA72-4	DE5071	ELISA
CA72-4	DE51100	IRMA
Calcitonin	DE16100	IRMA
Calcitonin ultra sensitive	DEKAP0421	ELISA
Calprotectin	DE843	Sample Collection Kit
Calprotectin	DE849	ELISA
Candida albicans IgG	DECAN01	ELISA
Candida albicans IgM	DECAN03	ELISA
Cardiolipin Ab IgA	DE7290	ELISA
Cardiolipin Ab IgG/IgM	DE7300	ELISA
Cardiolipin Screen	DE7310	ELISA
CCP Ab	DE7760	ELISA
CEA	DE1868	ELISA
CEA	DE38100	IRMA
Centromere B Ab	DE7320	ELISA
Chagas (Trypanosoma cruzi) IgG	DENO0114	ELISA
Chikungunya Virus IgG capture	DECHIG0590	ELISA
Chikungunya Virus IgM μ -capture	DECHIM0590	ELISA
Chromogranin A	DEE9000	ELISA
Corticosterone	DE4164	ELISA
Cortisol	DE28100	RIA
Cortisol	DEH3388	ELISA
Cortisol free in Saliva	DES6611	ELISA
Cortisol in urine	DE2989	ELISA

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Product	Cat.-No.	Method
C-Peptide	DE1293	ELISA
CRP	DE740001	ELISA
CYFRA 21-1	DE5070	ELISA
Dengue Virus IgG	DENG0120	ELISA
Dengue Virus IgM	DENM0120	ELISA
DGP Ab IgA	DE7770	ELISA
DGP Ab IgG	DE7780	ELISA
DHEA	DEH3344	ELISA
DHEA free in Saliva	DES6666	ELISA
DHEA-S	DEH3366	ELISA
Dihydrotestosterone (DHT)	DE2330	ELISA
Dihydrotestosterone (DHT)	DE5170	RIA
Diphtheria IgG	DEDIP01	ELISA
Dopamine	DEE6300	ELISA
ds-DNA Ab IgA	DE7340	ELISA
ds-DNA Ab IgG	DE7360	ELISA
ds-DNA Screen	DE7370	ELISA
EBV EA (Early Antigen) IgA	DEEBE02	ELISA
EBV EA (Early Antigen) IgG	DEEBE01	ELISA
EBV EA (Early Antigen) IgM	DEEBE03	ELISA
EBV EBNA-1 IgG	DEEBN01	ELISA
EBV EBNA-1 IgM	DEEBN03	ELISA
EBV VCA IgA	DEEBV02	ELISA
EBV VCA IgG	DEEBV01	ELISA
EBV VCA IgM	DEEBV03	ELISA
Echinococcus granulosus IgG	DEECH01	ELISA
ENA Combi	DE7390	ELISA
ENA Screen	DE7420	ELISA
ENA-6 Profile	DE7410	ELISA
Entamoeba histolytica IgG	DEENTG0140	ELISA
EPO (Erythropoietin)	DE3646	ELISA
Estradiol	DE4381	RIA
Estradiol	DEH3355	ELISA
Estradiol free in Saliva	DESLV4188	ELISA
Estradiol sensitive	DE4399	ELISA
Estriol free in Saliva	DES6644	ELISA
Estriol total	DE3717	ELISA
Estriol unconjugated	DE1612	ELISA
Estrone	DE4174	ELISA
Estrone free in Saliva	DESLV5228	ELISA
Ferritin	DE4408	ELISA
FOB (Fecal Occult Blood)	DE010A100	Rapid Test

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Product	Cat.-No.	Methode
FSH	DE1288	ELISA
GBM Ab	DE7130	ELISA
Giardia lamblia	DE610001	ELISA
Gliadin IgA	DEGLI02	ELISA
Gliadin IgG	DEGLI01	ELISA
Gliadin IgM	DEGLI03	ELISA
hCG	DE1469	ELISA
Helicobacter pylori IgA	DEHEL02	ELISA
Helicobacter pylori IgG	DEHEL01	ELISA
Helicobacter pylori IgM	DEHEL03	ELISA
Herpes simplex 1 IgG	DEHS101	ELISA
Herpes simplex 1 IgM	DEHS103	ELISA
Herpes simplex 1/2 IgG	DEHSV01	ELISA
Herpes simplex 1/2 IgM	DEHSV03	ELISA
Herpes simplex 2 IgG	DEHS201	ELISA
Herpes simplex 2 IgM	DEHS203	ELISA
hGH	DE3552	ELISA
Histamine	DEE1000	ELISA
Histamine Release	DEE1100	Supplementary Kit
Histone Ab	DE7670	ELISA
Homocysteine	DE2925	ELISA
Homocysteine	DE3329	Control Set
hPL	DE1283	ELISA
hsCRP	DE740011	ELISA
IFN-gamma human	DE4434	ELISA
IGFBP-1	DEE001	ELISA
IGFBP-2	DEE005	ELISA
IGFBP-3	DEE003A	ELISA
IGF-I	DEE020	ELISA
IGF-I 600	DE4140	ELISA
IGF-II	DEE030	ELISA
IgG4 Screen Nutritional 20	DE40496	ELISA
IgG4 Screen Nutritional 88	DE40188	ELISA
Influenza A IgG	DEIFA01	ELISA
Influenza A IgM	DEIFA03	ELISA
Influenza B IgG	DEIFB01	ELISA
Insulin	DE2935	ELISA
Insulin Ab	DE7430	ELISA
Interleukin-10 human	DE4699	ELISA
Interleukin-1beta human	DE4437	ELISA
Interleukin-6 human	DE4640	ELISA
Interleukin-8 human	DE4700	ELISA

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Product	Cat.-No.	Method
Intrinsic Factor Ab	DE7140	ELISA
Jo-1 Ab	DE7440	ELISA
Legionella pneumophila IgG	DELEGG0650	ELISA
Leishmania infantum IgG	DEIG0310	ELISA
Leptin	DEE007	ELISA
LH	DE1289	ELISA
Measles IgG	DEMAS01	ELISA
Measles IgM	DEMAS03	ELISA
Metanephrine Plasma	DEE8100	ELISA
Metanephrine Urine	DEE8400	ELISA
Micro-Albumin	DE7620	ELISA
Mumps IgG	DEMUM01	ELISA
Mumps IgM	DEMUM03	ELISA
Mycobacterium tuberculosis IgG	DETUB01	ELISA
Mycobacterium tuberculosis IgM	DETUB03	ELISA
Mycoplasma pneumoniae IgG	DEMYK01	ELISA
Mycoplasma pneumoniae IgM	DEMYK03	ELISA
Neopterin	DE59321	ELISA
Nephelines Plasma	DER8300	RIA
Nephelines Plasma	DEE8300	ELISA
Nephelines Urine	DEE8600	ELISA
Nephelines Urine	DER8600	RIA
Noradrenaline	DEE6200	ELISA
Normetanephrine Plasma	DEE8200	ELISA
Normetanephrine Urine	DEE8500	ELISA
NSE	DE2353	ELISA
Nucleosome Ab	DE7180	ELISA
Osteocalcin human	DEKAP1381	ELISA
Parainfluenza 1/2/3 IgG	DEPAX01	ELISA
Parainfluenza 1/2/3 IgM	DEPAX03	ELISA
Parietal Cell Ab	DE7450	ELISA
Parvovirus B19 IgG	DE3503	ELISA
Parvovirus B19 IgM	DE3504	ELISA
Phosphatidic Acid Ab IgG/IgM	DE7190	ELISA
Phosphatidyl Inositol Ab IgG/IgM	DE7200	ELISA
Phosphatidyl Serine Ab	DE7460	ELISA
Phospholipid Screen IgG/IgM	DE7470	ELISA
Plasma Renin Activity (PRA)	DEMSE5600	ELISA
PLGF (Placenta growth factor)	DE4529	ELISA
PMN Elastase	DEH3311	ELISA
Poliomyelitis Virus IgG	DEPOL01	ELISA
Progesterone	DE1561	ELISA

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Product	Cat.-No.	Methode
Proinsulin	DE1560	ELISA
Prolactin	DE1291	ELISA
Protein C	DE10901	ELISA
Protein S	DE10902	ELISA
Prothrombin Ab IgG/IgM	DE7210	ELISA
Prothrombin Screen	DE7230	ELISA
PTH intact	DE3645	ELISA
Renin	DE5125	ELISA
Resistin	DEE050	ELISA
Respiratory syncytial Virus (RSV) IgG	DERSV01	ELISA
Respiratory syncytial Virus (RSV) IgM	DERSV03	ELISA
RF-Absorbent 1 ml	DEMJS02	Component
RF-Absorbent 20 ml	DEMJS03	Component
Rheumatoid Factor IgA	DE7630	ELISA
Rheumatoid Factor IgG	DE7640	ELISA
Rheumatoid Factor IgM	DE7650	ELISA
Rheumatoid Factor Screen	DE7660	ELISA
RNP 70 Ab	DE7490	ELISA
RNP/Sm Ab	DE7500	ELISA
Schistosoma mansoni IgG	DESCHG0410	ELISA
Scl-70 Ab	DE7510	ELISA
Secretory IgA	DEXK276	ELISA
Serotonin	DEE8900	ELISA
SHBG	DE2996	ELISA
Sm Ab	DE7520	ELISA
SS-A 52 Ab	DE7530	ELISA
SS-A Ab	DE7550	ELISA
SS-B Ab	DE7560	ELISA
ss-DNA Ab	DE7570	ELISA
Strongyloides IgG/IgM	DESTRO0690	ELISA
T3 free	DE3801	ELISA
T3 free	DE06100	RIA
T3 free	DE06300	RIA
T3 total	DE4569	ELISA
T4 free	DE3775	ELISA
T4 free	DE07100	RIA
T4 free	DE07300	RIA
T4 total	DE4568	ELISA
Taenia solium IgG	DETAEG0420	ELISA
TBEV IgG	DEFSM01	ELISA
TBEV IgM	DEFSM03	ELISA
Testosterone	DE1559	ELISA

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Product	Cat.-No.	Methode
Testosterone	DE4386	RIA
Testosterone free	DE2924	ELISA
Testosterone free	DE4369	RIA
Testosterone free in Saliva	DES6622	ELISA
Tetanus Toxoid IgG	DETET01	ELISA
Thyreoidal Peroxidase-Ab (TPO-Ab)	DE7580	ELISA
Thyreoidal Peroxidase-Ab (TPO-Ab)	DE18100	RIA
Thyroglobulin (hTg)	DE20100	IRMA
Thyroglobulin (hTg)	DE7680	ELISA
Thyroglobulin-Ab (Tg-Ab)	DE47100	RIA
Thyroglobulin-Ab (Tg-Ab)	DE7590	ELISA
Tissue Transglutaminase Ab IgA	DE7720	ELISA
Tissue Transglutaminase Ab IgG	DE7730	ELISA
Tissue Transglutaminase Ab Screen	DE7740	ELISA
TNF-alpha human	DE4641	ELISA
Total IgE	DEIGE02	ELISA
Toxocara canis IgG	DE0450	ELISA
Treponema pallidum (Syphilis) IgG	DE3517	ELISA
Treponema pallidum (Syphilis) IgM	DE4267	ELISA
Trichinella spiralis IgG	DETRIG0480	ELISA
Tryptophan	DEE2700	ELISA
TSH	DE15100	IRMA
TSH	DE4171	ELISA
TSH	DE15300	IRMA
TSH-R-Ab	DE3369	ELISA
Varicella zoster IgG	DEVAR01	ELISA
Varicella zoster IgM	DEVAR03	ELISA
Yersinia enterocolitica IgA	DEYER02	ELISA
Yersinia enterocolitica IgG	DEYER01	ELISA
Yersinia enterocolitica IgM	DEYER03	ELISA
Zika Virus IgG capture	DEZVG0790	ELISA
Zika Virus IgM μ -capture	DEZVM0790	ELISA
end of list		