

**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 die 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 sind
- den Verpflichtungen des Anhang III (ausgenommen Kapitel 6) der EG-Richtlinie 98/79/EG vom 27. Oktober 1998 nachkommen
- allen übrigen relevanten Verpflichtungen der EG-Richtlinie 98/79/EG vom 27. Oktober 1998 genügen

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

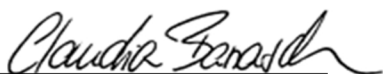
DIN EN ISO 13612
DIN EN ISO 15223-1
DIN EN ISO 18113-2

Demeditec has a Quality System in place based on EN ISO 9001:2008 and EN ISO 13485:2012, issued by mdc medical device certification GmbH.

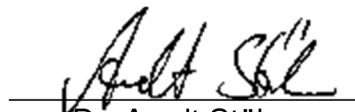
Demeditec ist zertifiziert nach EN ISO 9001:2008 und EN ISO 13485:20012 durch mdc medical device certification GmbH.

Valid until / gültig bis: 22.06.2020

Kiel-Wellsee, 06.04.2016



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	Method	Conformity
17-OH-Progesterone	DEH3322	ELISA	CE
17-OH-Progesterone	DE4372	RIA	CE
17-OH-Progesterone free in Saliva	DESLV3140	ELISA	CE
2 CAT	DEE6500	ELISA	CE
2 CAT	DER6500	RIA	CE
2 CAT Plasma	DEE4500	ELISA	CE
25-OH Vitamin D total	DE1971	ELISA	CE
25-OH Vitamin D total	DER1971	RIA	CE
25-OH Vitamin D3	DEKIP1961	RIA	CE
3 CAT	DER6600	RIA	CE
3 CAT	DEE6600	ELISA	CE
5 α -Androstane-3 α , 17 β -diol-Glucuronide Direct	DE4192	ELISA	CE
5-HIAA	DEE1900	ELISA	CE
ACPA	DE7170	ELISA	CE
ACTH	DE3647	ELISA	CE
ACTH	DE4735	IRMA	CE
Active-B12 (Holotranscobalamin)	DEFMABT100	ELISA	CE
Adenovirus IgG	DEADV01	ELISA	CE
Adenovirus IgM	DEADV03	ELISA	CE
Adiponectin human	DEE009	ELISA	CE
Adrenaline	DEE6100	ELISA	CE
Adrenaline	DER6100	RIA	CE
AFP	DE1468	ELISA	CE
Aldosterone	DE5298	ELISA	CE
Aldosterone	DERCW100	RIA	CE
Aldosterone	IT1664	RIA	CE
Alpha-Amylase Saliva	DEEQ6231	ELISA	CE
Alpha-Fodrin Ab IgG/IgA	DE7090	ELISA	CE
AMA-M2	DE7000	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-C (PR3) hs	DE7070	ELISA	CE
ANCA-P (MPO)	DE7080	ELISA	CE
Androstenedione	DE3265	ELISA	CE
Androstenedione	DE4388	RIA	CE
Androstenedione free in saliva	DESLV4780	ELISA	CE

Annex I

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Product	Cat.-No. Demeditec	Method	Conformity
Angiotensin I	IT3518	RIA	CE
Annexin V Ab IgG/IgM	DE7100	ELISA	CE
Anti-ASGPR IgG	DE4271	ELISA	CE
Anti-GAD	DEGAD100	RIA	CE
Anti-GAD	DEGDE96	ELISA	CE
Anti-IA2	DEIA2100	RIA	CE
Anti-IA2	DEIAE962	ELISA	CE
Anti-Insulin	DEIAA100	RIA	CE
Anti-LC-1	DE4276	ELISA	CE
Anti-LKM-1	DE7703	ELISA	CE
Anti-Ovarian Ab	DE2937	ELISA	CE
Anti-R-TSH Ab	DETCT100	RIA	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 IgA	DEASP02	ELISA	CE
Aspergillus fumigatus IgG	DEASP01	ELISA	CE
Aspergillus fumigatus IgM	DEASP03	ELISA	CE
Beta-2-Microglobulin	DE7610	ELISA	CE
Beta-2-Microglobulin	IT1113	RIA	CE
Bordetella pertussis FHA IgA	DEBPT08	ELISA	CE
Bordetella pertussis FHA IgG	DEBPT07	ELISA	CE
Bordetella pertussis IgA	DEBPT02	ELISA	CE
Bordetella pertussis IgG	DEBPT01	ELISA	CE
Bordetella pertussis IgM	DEBPT03	ELISA	CE
Bordetella pertussis toxin IgA	DE3449	ELISA	CE
Bordetella pertussis toxin IgG	DEBPT04	ELISA	CE
Bordetella pertussis toxin IgM	DE3451	ELISA	CE
Borrelia burgdorferi IgG	DEBOR01	ELISA	CE
Borrelia burgdorferi IgM	DEBOR03	ELISA	CE
BPI Ab	DE7110	ELISA	CE
Brucella abortus IgA	DEBRU02	ELISA	CE
Brucella abortus IgG	DEBRU01	ELISA	CE
Brucella abortus IgM	DEBRU03	ELISA	CE
C1q Ab	DE7280	ELISA	CE
C5a	DE3327	ELISA	CE
CA125	DE49100	IRMA	CE
CA125	DE5072	ELISA	CE
CA15-3	DE5068	ELISA	CE

Annex I

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Product	Cat.-No. Demeditec	Method	Conformity
CA15-3	DE53100	IRMA	CE
CA19-9	DE50100	IRMA	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	DE849	ELISA	CE
Calprotectin Sample Collecting Kit	DE843	sample collecting kit	CE
Candida albicans IgG	DECAN01	ELISA	CE
Candida albicans IgM	DECAN03	ELISA	CE
Cardiolipin Ab IgA	DE7290	ELISA	CE
Cardiolipin Ab IgG/IgM	DE7300	ELISA	CE
Cardiolipin Screen	DE7310	ELISA	CE
Cathepsin G Ab	DE7120	ELISA	CE
CBG (Cortisol binding Globulin)	DEKIP1809	RIA	CE
CCP Ab	DE7760	ELISA	CE
CEA	DE1868	ELISA	CE
CEA	DE38100	IRMA	CE
Centromere B Ab	DE7320	ELISA	CE
Chagas (Trypanosoma cruzi) IgG	DENO0114	ELISA	CE
Chikungunya Virus IgG capture	DECHIG0590	ELISA	CE
Chikungunya Virus IgM μ -capture	DECHIM0590	ELISA	CE
Chromogranin-A	DEE9000	ELISA	CE
CIC C1q	DE3169	ELISA	CE
Corticosterone	DE4164	ELISA	CE
Cortisol	DE28100	RIA	CE
Cortisol	DE1887	ELISA	CE
Cortisol free in Saliva	DES6611	ELISA	CE
Cortisol in urine	DE2989	ELISA	CE
C-Peptide	DE1293	ELISA	CE
C-Peptide	DE35100	IRMA	CE
CRP	DE740001	ELISA	CE
Cyclosporine, direct	IT3679	RIA	CE
Cyfra 21-1	DE5070	ELISA	CE
Cyfra 21-1	DE52100	IRMA	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

Annex I

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Product	Cat.-No. Demeditec	Method	Conformity
DHEA	DEH3344	ELISA	CE
DHEA	IT1138	RIA	CE
DHEA free in Saliva	DES6666	ELISA	CE
DHEA-S	DEH3366	ELISA	CE
DHEA-S	DE44100	RIA	CE
Dihydrotestosterone (DHT)	DE2330	ELISA	CE
Dihydrotestosterone (DHT)	DE5170	RIA	CE
Diphtheria IgG	DEDIP01	ELISA	CE
Dopamine	DEE6300	ELISA	CE
Dopamine	DER6300	RIA	CE
dsDNA Ab	DE19011	RIA	CE
ds-DNA Ab IgA	DE7340	ELISA	CE
ds-DNA Ab IgG	DE7360	ELISA	CE
ds-DNA Ab IgM	DE7350	ELISA	CE
ds-DNA Screen	DE7370	ELISA	CE
EBV EA (Early Antigen) IgA	DEEBE02	ELISA	CE
EBV EA (Early Antigen) IgG	DEEBE01	ELISA	CE
EBV EA (Early Antigen) IgM	DEEBE03	ELISA	CE
EBV EBNA-1 IgA	DEEBN02	ELISA	CE
EBV EBNA-1 IgG	DEEBN01	ELISA	CE
EBV EBNA-1 IgM	DEEBN03	ELISA	CE
EBV VCA IgA	DEEBV02	ELISA	CE
EBV VCA IgG	DEEBV01	ELISA	CE
EBV VCA IgM	DEEBV03	ELISA	CE
Echinococcus granulosus IgG	DEECH01	ELISA	CE
Elastase Ab	DE7380	ELISA	CE
ENA Combi	DE7390	ELISA	CE
ENA Screen	DE7420	ELISA	CE
ENA-4 Profile	DE7400	ELISA	CE
ENA-6 Profile	DE7410	ELISA	CE
Entamoeba histolytica Ag	DE4454	ELISA	CE
Entamoeba histolytica IgG	DEENTG0140	ELISA	CE
EPO (Erythropoietin)	DE3646	ELISA	CE
Estradiol	DEH3355	ELISA	CE
Estradiol	DE4381	RIA	CE
Estradiol free in Saliva	DESLV4188	ELISA	CE
Estradiol, sensitive	DE4399	ELISA	CE
Estriol free in Saliva	DES6644	ELISA	CE
Estriol, total	DE3717	ELISA	CE
Estriol, unconjugated	DE1612	ELISA	CE

Annex I

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Product	Cat.-No. Demeditec	Method	Conformity
Estrone	DE4174	ELISA	CE
Estrone free in saliva	DESLV5228	ELISA	CE
Ferritin	DE34100	IRMA	CE
Ferritin	DE4408	ELISA	CE
FOB (Fecal Occult Blood)	DE010A100	Rapid test	CE
FSH	DE1288	ELISA	CE
FSH	DE31100	IRMA	CE
GBM Ab	DE7130	ELISA	CE
Giardia lamblia	DE610001	ELISA	CE
Gliadin IgA	DEGLI02	ELISA	CE
Gliadin IgG	DEGLI01	ELISA	CE
Gliadin IgM	DEGLI03	ELISA	CE
Hb-Hp Combo	DE010A300	Rapid test	CE
hCG	DE1469	ELISA	CE
Helicobacter pylori Ag (stool)	DE4354	ELISA	CE
Helicobacter pylori IgA	DEHEL02	ELISA	CE
Helicobacter pylori IgG	DEHEL01	ELISA	CE
Helicobacter pylori IgM	DEHEL03	ELISA	CE
Herpes simplex 1 IgG	DEHS101	ELISA	CE
Herpes simplex 1 IgM	DEHS103	ELISA	CE
Herpes simplex 1/2 IgG	DEHSV01	ELISA	CE
Herpes simplex 1/2 IgM	DEHSV03	ELISA	CE
Herpes simplex 2 IgG	DEHS201	ELISA	CE
Herpes simplex 2 IgM	DEHS203	ELISA	CE
hGH	DE3552	ELISA	CE
hGH	DE43100	IRMA	CE
Histamine	DEE1000	ELISA	CE
Histamine	IT1659	RIA	CE
Histamine Cell Culture	DEE1700	ELISA	CE
Histone Ab	DE7670	ELISA	CE
Homocysteine	DE2925	ELISA	CE
Homocysteine Control Set	DE3329	Control	CE
hPL	DE1283	ELISA	CE
hsCRP	DE740011	ELISA	CE
ICA (Islet Cell Autoantibodies)	DE1594	ELISA	CE
IFN- γ human	DE228	ELISA	CE
IGF-1	A15729	IRMA	CE
IGF-1 600	DE4140	ELISA	CE
IGFBP-1	DEE001	ELISA	CE
IGFBP-2	DEE005	ELISA	CE

Annex I

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IGFBP-3	DE6600	IRMA	CE
IGFBP-3	DEE003A	ELISA	CE
IGF-I	DEE020	ELISA	CE
IGF-II	DEE030	ELISA	CE
IgG4 Screen Nutritional 20	DE40496	ELISA	CE
IgG4 Screen Nutritional 88	DE40188	ELISA	CE
Influenza A IgA	DEIFA02	ELISA	CE
Influenza A IgG	DEIFA01	ELISA	CE
Influenza A IgM	DEIFA03	ELISA	CE
Influenza B IgA	DEIFB02	ELISA	CE
Influenza B IgG	DEIFB01	ELISA	CE
Influenza B IgM	DEIFB03	ELISA	CE
Insulin	DE2935	ELISA	CE
Insulin	DE39100	IRMA	CE
Insulin Ab	DE7430	ELISA	CE
Interleukin-10 human	DE4699	ELISA	CE
Interleukin-12 p70 human	DE4843	ELISA	CE
Interleukin-1a human	DE2432	ELISA	CE
Interleukin-1 β human	DE4437	ELISA	CE
Interleukin-2 human	DE221	ELISA	CE
Interleukin-6 human	DE2132	ELISA	CE
Interleukin-8 human	DE4700	ELISA	CE
Intrinsic Factor Ab	DE7140	ELISA	CE
JE (Japanese Encephalitis) IgG	DE4518	ELISA	CE
JE (Japanese Encephalitis) IgM capture	DE4505	ELISA	CE
Jo-1 Ab	DE7440	ELISA	CE
Lactoferrin Ab	DE7160	ELISA	CE
Legionella IgG/IgM/IgA	DE2814	ELISA	CE
Leishmania infantum IgG	DEIG0310	ELISA	CE
Leptin	DEE007	ELISA	CE
LH	DE1289	ELISA	CE
LH	DE30100	IRMA	CE
Lipoprotein (a)	DEE59011	ELISA	CE
Lysozyme Ab	DE7150	ELISA	CE
Measles IgG	DEMAS01	ELISA	CE
Measles IgM	DEMAS03	ELISA	CE
Melatonin	DE1431	ELISA	CE
Melatonin Direct	DER3300	RIA	CE
Melatonin direct in saliva	DEEKDSM96	ELISA	CE
Metanephrine Plasma	DEE8100	ELISA	CE

Annex I

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Product	Cat.-No. Demeditec	Method	Conformity
Metanephrine Plasma	DER8100	RIA	CE
Metanephrine Urine	DEE8400	ELISA	CE
Metanephrine Urine	DER8400	RIA	CE
Mumps IgG	DEMUM01	ELISA	CE
Mumps IgM	DEMUM03	ELISA	CE
Mycobacterium tuberculosis IgG	DETUB01	ELISA	CE
Mycobacterium tuberculosis IgM	DETUB03	ELISA	CE
Mycoplasma pneumoniae IgA	DEMYK02	ELISA	CE
Mycoplasma pneumoniae IgG	DEMYK01	ELISA	CE
Mycoplasma pneumoniae IgM	DEMYK03	ELISA	CE
Neopterin	DE59321	ELISA	CE
Nephrines Plasma	DEE8300	ELISA	CE
Nephrines Plasma	DER8300	RIA	CE
Nephrines Urine	DEE8600	ELISA	CE
Nephrines Urine	DER8600	RIA	CE
Noradrenaline	DEE6200	ELISA	CE
Noradrenaline	DER6200	RIA	CE
Normetanephrine Plasma	DEE8200	ELISA	CE
Normetanephrine Plasma	DER8200	RIA	CE
Normetanephrine Urine	DEE8500	ELISA	CE
Normetanephrine Urine	DER8500	RIA	CE
Nucleosome Ab	DE7180	ELISA	CE
Osteocalcin human	DEKAP1381	ELISA	CE
Parainfluenza 1,2&3 IgA	DEPAX02	ELISA	CE
Parainfluenza 1,2&3 IgG	DEPAX01	ELISA	CE
Parainfluenza 1,2&3 IgM	DEPAX03	ELISA	CE
Parietal Cell Ab	DE7450	ELISA	CE
Parvovirus B19 IgG	DE3503	ELISA	CE
Parvovirus B19 IgM	DE3504	ELISA	CE
Phosphatidic Acid Ab IgG/IgM	DE7190	ELISA	CE
Phosphatidyl Inositol Ab IgG/IgM	DE7200	ELISA	CE
Phosphatidyl Serine Ab	DE7460	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
Poliomyelitis Virus IgG	DEPOL01	ELISA	CE
Pregnenolone direct	DE4170	ELISA	CE
Progesterone	DE1561	ELISA	CE
Progesterone	DE4494	RIA	CE

Annex I

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Product	Cat.-No. Demeditec	Method	Conformity
Progesterone free in Saliva	DES6633	ELISA	CE
Proinsulin	DE1560	ELISA	CE
Prolactin	DE1291	ELISA	CE
Prolactin	DE32100	IRMA	CE
Protein C	DE10901	ELISA	CE
Protein S	DE10902	ELISA	CE
Prothrombin Ab IgA	DE7220	ELISA	CE
Prothrombin Ab IgG/IgM	DE7210	ELISA	CE
Prothrombin Screen	DE7230	ELISA	CE
PTH	DE3649	IRMA	CE
PTH intact	DE3645	ELISA	CE
Renin	DE5125	ELISA	CE
Renin	DE5201	IRMA	CE
Resistin	DEE050	ELISA	CE
Respiratory syncytial virus (RSV) IgA	DERSV02	ELISA	CE
Respiratory syncytial virus (RSV) IgG	DERSV01	ELISA	CE
Respiratory syncytial virus (RSV) IgM	DERSV03	ELISA	CE
RF-Adsorbent 1 ml	DEMJS02	Component	CE
RF-Adsorbent 20 ml	DEMJS03	Component	CE
Rheumatoid Factor IgA	DE7630	ELISA	CE
Rheumatoid Factor IgG	DE7640	ELISA	CE
Rheumatoid Factor IgM	DE7650	ELISA	CE
Rheumatoid Factor Screen	DE7660	ELISA	CE
Rib-P Ab	DE7480	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
Secretory IgA	DEXK276	ELISA	CE
Serotonin	DEE8900	ELISA	CE
Serotonin	DER8900	RIA	CE
SHBG	DE2996	ELISA	CE
SHBG	DE46100	IRMA	CE
Sm Ab	DE7520	ELISA	CE
β 2-Glycoprotein I Ab IgA	DE7250	ELISA	CE
β 2-Glycoprotein I Ab IgG/IgM	DE7260	ELISA	CE
β 2-Glycoprotein I Screen	DE7270	ELISA	CE
SS-A 52 Ab	DE7530	ELISA	CE
SS-A 60 Ab	DE7540	ELISA	CE
SS-A Ab	DE7550	ELISA	CE

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Product	Cat.-No. Demeditec	Method	Conformity
SS-B Ab	DE7560	ELISA	CE
ss-DNA Ab	DE7570	ELISA	CE
β -hCG	DE1911	ELISA	CE
β -hCG	DE56100	IRMA	CE
Strongyloides IgG	DE4208	ELISA	CE
T3, free	DE06100	RIA	CE
T3, free	DE06300	RIA	CE
T3, free	DE2385	ELISA	CE
T3, total	DE4534	RIA	CE
T3, total	DE4569	ELISA	CE
T4, free	DE07100	RIA	CE
T4, free	DE07300	RIA	CE
T4, free	DE2386	ELISA	CE
T4, total	DE4533	RIA	CE
T4, total	DE4568	ELISA	CE
Taenia solium IgG	DETAEG0420	ELISA	CE
TBEV IgG	DEFSM01	ELISA	CE
TBEV IgM	DEFSM03	ELISA	CE
Testosterone	DE1559	ELISA	CE
Testosterone direct	DE4386	RIA	CE
Testosterone free	DE4369	RIA	CE
Testosterone free	DE2924	ELISA	CE
Testosterone free in Saliva	DES6622	ELISA	CE
Tetanus Toxoid IgG	DETET01	ELISA	CE
TGF-beta-1	DE1864	ELISA	CE
Thrombosis Profile	DE7600	ELISA	CE
Thymidine Kinase	IT1948	REA	CE
Thyreoidal Peroxidase-Ab (TPO-Ab)	DE03100	RIA	CE
Thyreoidal Peroxidase-Ab (TPO-Ab)	DE7580	ELISA	CE
Thyroglobulin (hTg)	DE20100	IRMA	CE
Thyroglobulin (hTg)	DE7680	ELISA	CE
Thyroglobulin-Ab (Tg-Ab)	DE02100	RIA	CE
Thyroglobulin-Ab (Tg-Ab)	DE7590	ELISA	CE
Tissue Transglutaminase Ab IgA	DE7720	ELISA	CE
Tissue Transglutaminase Ab IgG	DE7730	ELISA	CE
Tissue Transglutaminase Ab Screen	DE7740	ELISA	CE
TNF-alpha total human	DE2034	ELISA	CE
Total IgE	DEIGE02	ELISA	CE
Toxocara canis IgG	DE0450	ELISA	CE
TPA	DE2092	ELISA	CE

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Product	Cat.-No. Demeditec	Method	Conformity
TPA	DE3437	IRMA	CE
Treponema pallidum (Syphilis) IgG	DE3517	ELISA	CE
Treponema pallidum (Syphilis) IgM	DE4267	ELISA	CE
Trichinella spiralis IgG	DETRIG0480	ELISA	CE
Troponin I (cTnI)	DE004D098	Rapid test	CE
Tryptophan	DEE2700	ELISA	CE
TSH	DE4171	ELISA	CE
TSH 1h	DE15100	IRMA	CE
TSH 1h	DE15300	IRMA	CE
TSH-R-Ab	DE3369	ELISA	CE
Varicella zoster IgA	DEVAR02	ELISA	CE
Varicella zoster IgG	DEVAR01	ELISA	CE
Varicella zoster IgM	DEVAR03	ELISA	CE
Yersinia enterocolitica IgA	DEYER02	ELISA	CE
Yersinia enterocolitica IgG	DEYER01	ELISA	CE
Yersinia enterocolitica IgM	DEYER03	ELISA	CE
ZnT8 Ab	DEZNT896	ELISA	CE

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