

EC DECLARATION OF CONFORMITY

according to Directive 98/79/EC of the European Parliament and of the council of 27 October 1998
on *in vitro* diagnostic medical devices
in combination with article 110 of Regulation (EU) 2017/746 of the European Parliament and of the
Council of 5 April 2017

We, **DRG Instruments GmbH**, Frauenbergstr. 18, 35039 Marburg, Germany

herewith declare under our own responsibility that the products listed in the table below,

which are classified as miscellaneous products under Directive 98/79/EC

are in accordance with the requirements of the IVD Directive 98/79/EC annex I and III of the European Parliament in regard to the *in vitro* diagnostic medical devices (IVDs) and therefore are allowed to be CE marked.

Quality Management

DRG Instruments GmbH has established a Quality Management System for the design/development, production and distribution of *in vitro* diagnostic according to **EN ISO 13485:2016**.

Disclaimer

This Declaration of Conformity was created after the Date of Application of IVDR (May 26th, 2022). However, the cause for the creation of this Declaration of Conformity is NOT considered a "significant change" according to IVDR in combination with MDCG 2022-6 and therefore, the device continues to comply to IVDD.

Marburg, 2023-10-23



Dr. Matthias Herkert
PRRC

Product Name	DRG Cat.-No
FSH ELISA	EIA-1288
LH-Serum ELISA	EIA-1289
Prolactin ELISA	EIA-1291
17-OH Progesterone ELISA	EIA-1292
C-Peptide ELISA	EIA-1293
AFP	EIA-1468
HCG ELISA	EIA-1469
Testosterone ELISA	EIA-1559
Progesterone ELISA	EIA-1561

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Product Name	DRG Cat.-No
DHEA-S ELISA	EIA-1562
Free Estriol ELISA	EIA-1612
Immunoglobulin E (IgE) ELISA	EIA-1788
Sperm Antibody ELISA	EIA-1826
TGF- β 1 ELISA	EIA-1864
CEA ELISA	EIA-1868
Cortisol ELISA	EIA-1887
Anti-GAD ELISA	EIA-1910
β -HCG ELISA	EIA-1911
Helicobacter pylori IgM ELISA	EIA-2111
TGF- β 2 ELISA	EIA-2396
Estradiol ELISA	EIA-2693
Free Testosterone ELISA	EIA-2924
Insulin ELISA	EIA-2935
SHBG ELISA	EIA-2996
CIC C1q ELISA	EIA-3169
Androstenedione ELISA, 96 well	EIA-3265
Osteocalcin ELISA	EIA-3375
Thyroglobulin ELISA	EIA-3377
Adenovirus IgA ELISA	EIA-3445
Adenovirus IgG ELISA	EIA-3446
Adenovirus IgM ELISA	EIA-3447
Bordetella pertussis IgA ELISA, 96 well	EIA-3449
Bordetella pertussis IgG ELISA	EIA-3450
Bordetella pertussis IgM ELISA	EIA-3451
Brucella IgG ELISA, 96 Well	EIA-3455
Brucella IgM ELISA	EIA-3456
Candida albicans IgA ELISA	EIA-3457
Candida albicans IgG ELISA	EIA-3458
Candida albicans IgM ELISA	EIA-3459
Giardia lamblia Ag (stool) ELISA,	EIA-3477
Helicobacter pylori IgA ELISA	EIA-3483
Helicobacter pylori IgG ELISA	EIA-3484
HSV-1 IgG ELISA	EIA-3485

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Product Name	DRG Cat.-No
HSV-1 IgM ELISA	EIA-3486
HSV-2 IgG ELISA	EIA-3487
HSV-2 IgM ELISA	EIA-3488
HSV-1+2 IgG ELISA, 96 well	EIA-3489
HSV-1+2 IgM ELISA	EIA-3490
Mycoplasma pneumoniae IgG ELISA	EIA-3499
Mycoplasma pneumoniae IgM ELISA	EIA-3500
Tetanus toxin IgG ELISA	EIA-3514
Treponema pallidum IgG ELISA	EIA-3517
hGH ELISA	EIA-3552
Anti TPO Ab ELISA	EIA-3561
Anti-Centromere B ELISA	EIA-3569
Anti-Cardiolipin IgG/IgM ELISA	EIA-3587
Anti-Phospholipid Screen IgG/IgM ELISA, 96 well	EIA-3591
Anti-Gliadin IgG ELISA, 96 well	EIA-3605
Anti-Gliadin IgA ELISA	EIA-3606
Anti-Insulin ELISA	EIA-3608
Anti-Tissue-Transglutaminase IgA ELISA	EIA-3611
ACTH (Adrenocorticotrophic Hormone) ELISA	EIA-3647
Calcitonin	EIA-3648
Anti TG Ab ELISA	EIA-3708
Free T4 ELISA	EIA-3775
Free T3 ELISA	EIA-3801
Measles Virus IgG ELISA	EIA-3844
Measles Virus IgM ELISA	EIA-3845
Mumps Virus IgG ELISA	EIA-3846
Mumps Virus IgM ELISA	EIA-3847
Mycoplasma pneumoniae IgA ELISA	EIA-3848
Anti-Tissue-Transglutaminase IgG ELISA	EIA-3882
Histamine ELISA	EIA-4005
TSH ELISA	EIA-4171
EBV-EBNA-1 IgG ELISA (qualitative)	EIA-4246
EBV-EBNA-1 IgM ELISA (qualitative)	EIA-4247
Treponema pallidum IgM ELISA	EIA-4267

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Product Name	DRG Cat.-No
Ferritin ELISA	EIA-4408
EBV VCA IgA ELISA (qualitative)	EIA-4472
PLGF ELISA	EIA-4529
Mycoplasma hominis IgG ELISA	EIA-4559
Mycoplasma hominis IgM ELISA	EIA-4560
Ureaplasma urealyticum IgM ELISA	EIA-4561
T4 Total ELISA	EIA-4568
T3 Total ELISA	EIA-4569
NSE ELISA	EIA-4610
Ureaplasma urealyticum IgG ELISA	EIA-4623
TM-CA 15-3 ELISA	EIA-5068
TM-CA 19-9 ELISA	EIA-5069
TM-CYFRA 21-1 ELISA	EIA-5070
TM-CA 72-4 ELISA	EIA-5071
TM-CA 125 ELISA	EIA-5072
Mycoplasma hominis IgA ELISA	EIA-5097
Ureaplasma urealyticum IgA ELISA	EIA-5098
Calprotectin (Serum) ELISA	EIA-5111
Procalcitonin (Human) ELISA	EIA-5291
Aldosterone ELISA	EIA-5298
Anti-CCP ELISA	EIA-5653
Anti-C1q ELISA	EIA-5762
Strongyloides IgG/IgM ELISA	EIA-5812
Folic Acid ELISA	EIA-5847
Hanta Virus IgG ELISA	EIA-5858
Hanta Virus IgM ELISA	EIA-5859
Aspergillus fumigatus IgG ELISA	EIA-6129
Aspergillus fumigatus IgM ELISA	EIA-6130
AMH (Anti-Mullerian Hormone)	EIA-6141
Estriol total ELISA	EIA-6193
EBV (EA) IgG ELISA	EIA-6203
EBV (EA) IgM ELISA	EIA-6204
end of list	