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KONFORMITÄTSERKLÄRUNG / DECLARATION DE CONFORMITE / DICLARATIONE DE CONFORMITA / DECLARATION OF CONFORMITY

Name und Adresse der Firma
Nom et adresse de léntreprise
Nome e indirizzo della ditta
Name and address of the firm

MIKROGEN GmbH
Floriansbogen 2- 4
82061 Neuried

Wir erklären in alleiniger Verantwortung, dass die genannten Medizinprodukte für die In-vitro-Diagnostik

Nous déclarons sous notre propre responsibilité que les dispositifs médicaux de diagnostique in vitro décrits

Dichiariamo sooto propria responsibilitá che il dispositivo medico-diagnostico in vitro descritti

We declare on our own responsibility that the in vitro diagnostic medical devices described

Bezeichnung, Typ oder Modell, Chargen- oder Serien-Nr., ev. Herkunft
Nom, type ou modél, numéro de lot ou série, év. Source et nombre d´exemplaires
Nome, tipo o modello, numero di lotto o di serie, ev. Fonte e numero di esemplari
Name, type or model, batch or serial number, possibly sources and number of items

***recom*Blot: Rubella** IgG

***recom*Line: ANA/ENA** IgG; **Bordetella pertussis** IgG, -IgA; **Borrelia** IgG, -IgM; **Campylobacter** IgG, -IgA; **Chlamydia** IgG, -IgA [IgM]; **CMV** IgG [Avidity],-IgM; **EBV** IgG [Avidity] [IgA], -IgM; **HantaPlus** IgG, -IgM; **HCV** IgG; **Helicobacter** IgG **2.0**, -IgA **2.0**; **HEV** IgG/IgM; **HIV-1 & HIV-2** IgG; **HSV-1 & HSV-2** IgG; **Parvovirus B19** IgG [Avidity], -IgM; **SARS-CoV-2** IgG; **TORCH Screening** IgG, -IgM; **Toxoplasma** IgG [Avidity], -IgM [IgA]; **Treponema** IgG, -IgM; **Tropical Fever** IgG, -IgM; **Yersinia** IgG **2.0**, -IgA [IgM] **2.0**

***recom*Well: Borrelia** IgG, -IgM; **Campylobacter** IgG, -IgA; **Chlamydia trachomatis** IgG, -IgA; **Chlamydia pneumoniae** IgG, -IgA, IgM; **EBV** EBNA IgG, - VCA IgG, - EA IgG, - IgM; **Helicobacter** IgG, -IgA; **HEV** IgG, -IgM; **HPV 16/18/45**; **Parvovirus B19** IgG, -IgM; **SARS-CoV-2** IgG, -IgA; **Treponema** IgG, -IgM; **Yersinia** IgG, -IgA, -IgM

***recom*Bead: Bordetella pertussis** IgG **2.0**, -IgA **2.0**; **Borrelia** IgG **2.0**, -IgM **2.0**; **CXCL13**; **EBV** IgG **2.0**, -IgM **2.0**; **Treponema** IgG **2.0**, -IgM **2.0**; **Yersinia** IgG **2.0**, -IgA [IgM] **2.0**

***ampli*Cube: Coronavirus Panel**; **Coronavirus SARS-CoV-2**; **Gastrointestinal Bacterial Panel 1**; **Gastrointestinal Bacterial Panel 2**; **Gastrointestinal Viral Panel 1**; **Gastrointestinal Viral Panel 2**; **HEV 2.0 Quant**; **MDR Panel 1; MDR Panel 2; MDR Panel 3**; **MDR Panel 4**; **MDR Panel 5**; **MDR Panel 6**; **Respiratory Bacterial Panel 1**; **Respiratory Bacterial Panel 2**; **Respiratory Bacterial Panel 3**; **Respiratory Bacterial Panel 4**; **Respiratory Flu & SARS-CoV-2**; **Respiratory Flu & SARS-CoV-2 LC**; **Respiratory Viral Panel 1**; **Respiratory Viral Panel 2**; **Respiratory Viral Panel 3**; **Respiratory Viral Panel 4**; **Respiratory Viral Panel 5**; **SARS-CoV-2 Variants**; **STD Panel 1**; **STD Panel 2**; **STD Panel 3**; **Zika Virus**

***recom*Dot: Borrelia** IgG, -IgM; **EBV** IgG, -IgM; **Treponema** IgG, -IgM

CHLAMYCHECK® OPTIMA IgG, -IgA [IgM]

Control sera (test independent):
***positive*:** ANA/ENA IgG; Bordetella pertussis IgG, IgA; Borrelia IgG, IgM; Campylobacter IgG, IgA; Chlamydia IgG, IgA; CMV IgG, IgM; EBV IgG, IgA, IgM; Hantavirus IgG, IgM; Helicobacter IgG, IgA; HEV IgG, IgM; HSV IgG; Parvovirus IgG, IgM; Rubella IgG; SARS-CoV-2 IgG; Toxoplasma IgG, IgM; Treponema IgG, IgM; Yersinia IgG, IgA, IgM
negative: ANA/ENA IgG; Bordetella pertussis IgG/IgA; Borrelia IgG/IgM; Campylobacter IgG/IgA; Chlamydia IgG/IgA; CMV IgG/IgM; EBV IgG/IgM/IgA; Hantavirus IgG/IgM; Helicobacter IgG/IgA; HEV IgG/IgM; HSV IgG; Parvovirus IgG/IgM; SARS-CoV-2 IgG; Toxoplasma IgG/IgM; Treponema IgG/IgM; Yersinia IgG/IgM/IgA

Klassifizierung nach der Richtlinie über In-vitro-Diagnostika 98/79/EG

Classification selon la directive relative aux dispositifs médicaux de diagnostic in vitro 98/79/CE

Classificazione secondo la direttiva relativa ai dispositivi medico-diagnostici in vitro 98/79/CE

Classification according to the directive on in vitro diagnostic medical devices 98/79/EC

Produkt der Liste A, Anhang II
/Dispositif de la liste A, annexe II / Dispositivo dell´elenco A, allegato II / Device of list A, Annex II:
***recom*Line: HCV** IgG; ***recom*Line HIV-1 &HIV-2** IgG

Produkt der Liste B, Anhang II
Dispositif de la liste B, annexe II / Dispositivo dell´elenco B, allegato II / Device of list B, Annex II:
***recom*Blot: Rubella** IgG
***recom*Line: Chlamydia** IgG, -IgA [IgM]; **CMV** IgG [Avidity], **-**IgM; **TORCH Screening** IgG**, -**IgM; **Toxoplasma** IgG [Avidity]**, -**IgM [IgA];
***recom*Well : Chlamydia trachomatis** IgG, -IgA; **Chlamydia pneumoniae** IgG, -IgA, -IgM;
***ampli*Cube: Respiratory Bacterial Panel 1; STD Panel 1**
CHLAMYCHECK® IgG, - IgA [IgM]
control sera: *positive:* Chlamydia IgG, IgA; CMV IgG, IgM; Rubella IgG; Toxoplasma IgG, IgM
negative: Chlamydia IgG/IgA; CMV IgG/IgM; Toxoplasma IgG/IgM
Produkt zur Eigenanwendung, das nicht in Anhang II genannt ist
Dispositif destiné à l´autodiagnostic non listé dans l´annexe II / Dispositivo per testautodiagnostico non elencato nell´allegato / Device for self testing not listed in Annex II:
-

Sonstiges Produkt / Autre dispositif / Altro dispositivo / Other device
***recom*Line: ANA/ENA** IgG; **Bordetella pertussis** IgG, -IgA; **Borrelia** IgG, -IgM; **Campylobacter** IgG, -IgA; **EBV** IgG [Avidity] [IgA], -IgM; **HantaPlus** IgG, -IgM; **Helicobacter** IgG **2.0**, -IgA **2.0**; **HEV** IgG/IgM; **HSV-1 & HSV-2** IgG; **Parvovirus B19** IgG [Avidity], -IgM; **SARS-CoV-2** IgG; **Treponema** IgG, -IgM; **Tropical Fever** IgG, -IgM; **Yersinia** IgG **2.0**, -IgA [IgM] **2.0**
***recom*Well: Borrelia** IgG, -IgM; **Campylobacter** IgG, -IgA; **EBV** EBNA IgG, - VCA IgG, - EA IgG, - IgM; **Helicobacter** IgG, -IgA; **HEV** IgG, -IgM; **HPV 16/18/45**; **Parvovirus B19** IgG, -IgM; **SARS-CoV-2** IgG, -IgA; **Treponema** IgG, -IgM; **Yersinia** IgG, -IgA, -IgM
***recom*Bead: Bordetella pertussis** IgG **2.0**, -IgA **2.0**; **Borrelia** IgG **2.0**, -IgM **2.0**; **CXCL13**; **EBV** IgG **2.0**, -IgM **2.0**; **Treponema** IgG **2.0**, -IgM **2.0**; **Yersinia** IgG **2.0**, -IgA [IgM] **2.0**
***ampli*Cube: Coronavirus Panel**; **Coronavirus SARS-CoV-2**; **Gastrointestinal Bacterial Panel 1**; **Gastrointestinal Bacterial Panel 2**; **Gastrointestinal Viral Panel 1**; **Gastrointestinal Viral Panel 2**; **HEV 2.0 Quant**; **MDR Panel 1**; **MDR Panel 2**; **MDR Panel 3**; **MDR Panel 4; MDR Panel 5**; **MDR Panel 6**; **Respiratory Bacterial Panel 2**; **Respiratory Bacterial Panel 3**; **Respiratory Bacterial Panel 4; Respiratory Flu & SARS-CoV-2**; **Respiratory Flu & SARS-CoV-2 LC**; **Respiratory Viral Panel 1**; **Respiratory Viral Panel 2**; **Respiratory Viral Panel 3**; **Respiratory Viral Panel 4**; **Respiratory Viral Panel 5**; **SARS-CoV-2 Variants**; **STD Panel 2**; **STD Panel 3**; **Zika Virus**
***recom*Dot: Borrelia** IgG, -IgM; **EBV** IgG, -IgM; **Treponema** IgG, -IgM
Control sera (test independent):
***positive*:** ANA/ENA IgG; Bordetella pertussis IgG, IgA; Borrelia IgG, IgM; Campylobacter IgG, IgA; EBV IgG, IgA, IgM; Hantavirus IgG, IgM; Helicobacter IgG, IgA; HEV IgG, IgM; HSV IgG; Parvovirus IgG, IgM; SARS-CoV-2 IgG; Treponema IgG, IgM; Yersinia IgG, IgA, IgM
negative: ANA/ENA IgG; Bordetella pertussis IgG/IgA; Borrelia IgG/IgM; Campylobacter IgG/IgA; EBV IgG/IgM/IgA; Hantavirus IgG/IgM; Helicobacter IgG/IgA; HEV IgG/IgM; HSV IgG; Parvovirus IgG/IgM; SARS-CoV-2 IgG; Treponema IgG/IgM; Yersinia IgG/IgM/IgA

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Geschäftsführer: Dr. Erwin Soutschek
Sitz der Gesellschaft: Neuried (München)
Reg.-Gericht: München HRB Nr. 87312
USt.-Nr. Mikrogen GmbH: DE129416542

allen Anforderungen der Richtlinie über In-vitro-Diagnostika 98/79/EG entsprechen, die anwendbar sind.

remplissent toutes les exigences de la directive aux dispositifs médicaux de diagnostic in vitro 98/79/CE qui le concernent.

soddisfano tutte le disposizioni della direttiva relativa ai dispositivi medico-diagnostici in vitro 98/79/CE che lo riguardano.

meets all the provisions of the directive on diagnostic medical devices 98/79/EC which apply to it.

Angewandte gemeinsame technische Spezifikationen, harmonisierte Normen, nationale Normen oder andere normative Dokumente Spécifications techniques communes, normes harmonisées, normes nationales et autres documents normatifs appliqués Specifiche tecniche comuni, norme armonizzate o nazionali applicate, altri documenti normativi applicati Applied common technical specifications, harmonised standards, national standards or other normative documents	See list external documents (QM-documentation) available on request, (including medical device act, IVD 98/79/EG, MPG, harmonised standards, **CTS (HCV), CTS (HIV),** **DIN EN ISO 13485, ISO 13485 (MDSAP)**
Konformitätsbewertungsverfahren Procédure d´evaluation de la conformité Procedimento di valutazione della conformità Conformity assessment procedure	Test specific **Annex IV:** Annex II - products **Annex III:** all other tests
Benannte Stelle Notified body Organisme notifié Organo notificato	**mdc medical device certification GmbH**, Stuttgart

Neuried, 04.05.2021

Account for payments in US Dollar: