


Declaration of Conformity

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|  | MIKROGEN GmbH Floriansbogen 2-4 82061 Neuried Germany |
| SRN | DE-MF-000027747 |

We declare on our own responsibility that the products listed below meet the provisions of the directive on diagnostic medical devices 98/79/EC which apply to it.

Risk class: Annex II, List A

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| <i>recomLine</i> | HCV IgG; HIV-1 & HIV-2 IgG; HTLV-1 & HTLV-2 IgG |
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Risk class: Annex II, List B

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| <i>recomBlot</i> | Rubella IgG |
| <i>recomLine</i> | Chlamydia IgG; Chlamydia IgA [IgM]; CMV IgG [Avidität]; CMV IgM; TORCH Screening IgG; TORCH Screening IgM; Toxoplasma IgG [Avidität]; Toxoplasma IgM [IgA] |
| <i>recomWell</i> | Chlamydia trachomatis IgG; Chlamydia trachomatis IgA; Chlamydia pneumoniae IgG; Chlamydia pneumoniae IgA; Chlamydia pneumoniae IgM |
| <i>ampliCube</i> | Respiratory Bacterial Panel 1; Respiratory Bacterial Panel 1.1; Respiratory Bacterial Panel 1.1 LC; STD Panel 1 |
| Positive Control | Chlamydia IgG; Chlamydia IgA; Rubella IgG; CMV IgG; CMV IgM; Toxoplasma IgG; Toxoplasma IgM |
| Negative Control | Chlamydia IgG/IgA; CMV IgG/IgM; Toxoplasma IgG/IgM |

Risk class: General

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| <i>recomLine</i> | ANA/ENA IgG; Bordetella pertussis IgG; Bordetella pertussis IgA; Borrelia IgG; Borrelia IgM; Campylobacter IgG; Campylobacter IgA; EBV IgG [Avidität] [IgA]; HantaPlus IgG; HantaPlus IgM; Helicobacter IgG 2.0; Helicobacter IgA 2.0; HEV IgG/IgM; HSV-1 & HSV-2 IgG; Parvovirus B19 IgG [Avidität]; Parvovirus B19 IgM; SARS-CoV-2 IgG [Avidität]; Treponema IgG; Treponema IgM; Tropical Fever IgG; Tropical Fever IgM; Yersinia IgG 2.0; Yersinia IgA [IgM] 2.0 |
| <i>recomWell</i> | Borrelia IgG; Borrelia IgM; Campylobacter IgG; Campylobacter IgA; EBV EBNA IgG; EBV VCA IgG; EBV EA IgG; Helicobacter IgG; Helicobacter IgA; HEV IgG; HEV IgM; HPV 16/18/45; Parvovirus B19 IgG; Parvovirus B19 IgM; SARS-CoV-2 IgG; SARS-CoV-2 IgA; Treponema IgG; Treponema IgM; Yersinia IgG; Yersinia IgA; Yersinia IgM |
| <i>recomBead</i> | Bordetella pertussis IgG 2.0; Bordetella pertussis IgA 2.0; Borrelia IgG 2.0; Borrelia IgM 2.0; CXCL13; EBV IgG 2.0; EBV IgG 2.0; Treponema IgG 2.0; Treponema IgM 2.0; Yersinia IgG 2.0; Yersinia IgA [IgM] 2.0 |
| <i>ampliCube</i> | Coronavirus Panel; Coronavirus SARS-CoV-2; Coronavirus SARS-CoV-2 plus; 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; STD Panel 2; STD Panel 2.1; STD Panel 2.1 LC; STD Panel 3 |
| <i>recomDot</i> | Borrelia IgG; Borrelia IgM; EBV IgG; EBV IgM; Helicobacter IgG; Helicobacter IgA; Treponema IgG; Treponema IgM; Yersinia IgG; Yersinia IgA; Yersinia IgM |
| T-Track® | CMV; CMV Calculator; TB (TB Stimulation, TB Quant PCR); SARS-CoV-2 (SARS-CoV-2 Stimulation, SARS-CoV-2 Quant PCR) |
| Positive Control | ANA/ENA IgG; Bordetella pertussis IgG; Bordetella pertussis IgA; Borrelia IgG; Borrelia IgM; Campylobacter IgG; Campylobacter IgA; EBV IgG; EBV IgA; EBV IgM; Hantavirus IgG; Hantavirus IgM; Helicobacter IgG; Helicobacter IgA; HEV IgG; HEV IgM; HSV IgG; Parvovirus IgG; Parvovirus IgM; SARS-CoV-2 IgG; Treponema IgG; Treponema IgM; Yersinia IgG; Yersinia IgA; Yersinia IgM |
| Negative Control | 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 |

We declare on our own responsibility that the products listed below meet the provisions of the regulation (EU) 2017/746 on *in vitro* diagnostic medical devices which apply to it.

Risk class: A

| Name (German) | Name (English) | Basic UDI-DI |
|---|--|-----------------|
| <i>recomBead</i> Anti-human IgG Konjugat | <i>recomBead</i> Anti-human IgG conjugate | 42505711B2101WG |
| <i>recomBead</i> Anti-human IgM Konjugat | <i>recomBead</i> Anti-human IgM conjugate | 42505711B2101WG |
| <i>recomBead</i> Anti-human IgA Konjugat | <i>recomBead</i> Anti-human IgA conjugate | 42505711B2101WG |
| <i>recomDot</i> Anti-human IgG Konjugat | <i>recomDot</i> Anti-human IgG conjugate | 42505711B2101WG |
| <i>recomDot</i> Anti-human IgM Konjugat | <i>recomDot</i> Anti-human IgM conjugate | 42505711B2101WG |
| <i>recomDot</i> Anti-human IgA Konjugat | <i>recomDot</i> Anti-human IgA conjugate | 42505711B2101WG |
| <i>recomLine, recomBlot</i> Anti-human IgG Konjugat | <i>recomLine, recomBlot</i> Anti-human IgG conjugate | 42505711B2101WG |
| <i>recomLine</i> Anti-human IgM Konjugat | <i>recomLine</i> Anti-human IgM conjugate | 42505711B2101WG |
| <i>recomLine</i> Anti-human IgA Konjugat | <i>recomLine</i> Anti-human IgA conjugate | 42505711B2101WG |
| <i>recomBead</i> Wasch- und Verdünnungspuffer 6x | <i>recomBead</i> Wash- and Dilution buffer 6x | 42505711B2100WE |
| <i>recomBlot</i> Waschpuffer C 5x | <i>recomBlot</i> Wash buffer C 5x | 42505711B2100WE |
| <i>recomBlot, recomLine</i> Waschpuffer A (10x) | <i>recomBlot, recomLine</i> Wash buffer A (10x) | 42505711B2100WE |
| <i>recomLine</i> Verdünnungspuffer | <i>recomLine</i> Dilution buffer | 42505711B2100WE |
| <i>recomLine</i> Aviditätsreagenz | <i>recomLine</i> Avidity reagent | 42505711B2100WE |
| <i>recomLine</i> Milchpulver | <i>recomLine</i> Skim Milk Powder | 42505711B2100WE |
| <i>recomDot</i> Waschpuffer A (10x) | <i>recomDot</i> Wash buffer A 10x | 42505711B2100WE |
| <i>recomDot</i> Verdünnungspuffer | <i>recomDot</i> Dilution buffer | 42505711B2100WE |
| <i>recomWell</i> Waschpuffer 10x | <i>recomWell</i> Wash buffer 10x | 42505711B2100WE |
| <i>recomWell</i> Verdünnungspuffer | <i>recomWell</i> Dilution buffer | 42505711B2100WE |
| <i>recomBlot, recomLine</i> Substrat TMB prec. | <i>recomBlot, recomLine</i> Substrate TMB prec. | 42505711B2102WJ |
| <i>recomDot</i> Substrat TMB prec. | <i>recomDot</i> Substrate TMB prec. | 42505711B2102WJ |
| <i>recomWell</i> Substrate TMB fast2 | <i>recomWell</i> Substrate TMB fast2 | 42505711B2102WJ |
| <i>recomWell</i> Stopplösung | <i>recomWell</i> Stop solution | 42505711B2102WJ |



Dr. Erwin Soutschek
Managing Director
Mikrogen GmbH

Neuried, 10.11.2022

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I hereby certify that this document was signed in my presence
by Mr. Dr. Erwin Soutschek,
born on 02.02.1955,
resident at 82335 Berg, OT Farchach, Nikolausstr. 6 A,
personally known to me

acting on behalf of

Mikrogen GmbH
82061 Neuried, Floriansbogen 2 - 4,

as this company's director.

Landshut, 14.11.2022


Markus Hamp,
Notary



Kostenvermerk:

Gebühr gemäß Anlage
zu § 4 JVKostG
KV-JVKostG 1310

25,00 Euro



Die Echtheit vorstehender Unterschrift des
Notars Markus Hamp und die Echtheit des
beigedruckten Dienstsiegels werden hiermit
bestätigt.

Zugleich wird bescheinigt, dass der
Vorgenannte zur Vornahme der
Amtshandlung befugt war.

Landshut, 24. November 2022

Der Präsident des Landgerichts Landshut


Dr. Clemens Prokop
Präsident des Landgerichts