QUIDEL
Specialty Products

DECLARATION OF CONFORMITY

A027 **MicroVue™ Bb Plus Fragment EIA** (Complement)
(contains: A9948 – A9952, Bb Plus Standards; A9953/A9955, Bb Plus Low/High Controls; A9559, Microassay Plate; A9947, Stop Solution; A9957, 20X Wash Buffer; A3670, Complement Specimen Diluent; 5059, TMB Substrate; A9956, Bb Plus Conjugate; A3675, Hydrating Reagent)

Description: The MicroVue Bb Plus Enzyme Immunoassay Kit measures the amount of the complement fragment Bb, an activation fragment of Factor B of the alternative pathway of complement, in human plasma or serum. Measurement of Bb in human plasma or serum provides evidence of the involvement of the alternative pathway of complement. Measurement of alternative pathway activation aids in the diagnosis of several kidney diseases, e.g., chronic glomerulonephritis, lupus nephritis, as well as several skin diseases, e.g., dermititis herpetiform is and pemphigus vulgaris. Other diseases in which activation of the alternative pathway of complement has been observed include rheumatoid arthritis, sickle cell anemia, and gram-negative bacterial infections.

We, QUIDEL Corporation ensure and declare with sole responsibility, that the above-mentioned products meet the provisions of Council Directive 98/79/EC (IVD directive) as transposed into national regulation.

Wir, QUIDEL Corporation, stellen sicher und erklären mit alleiniger Verantwortung, dass die oben erwähnten Produkte die Bestimmungen der Richtlinie 98/79/EC (IVD-Richtlinie), umgesetzt in nationales Recht, erfüllen.

Nous soussignés, QUIDEL Corporation assurons et déclarons que les produits mentionnés ci-dessus sont en conformité avec la directive européenne 98/79/CE (directive sur les dispositifs médicaux de diagnostic in vitro) en tant que transposée dans la réglementation nationale.

Noi QUIDEL Corporation sono i soli responsabili, assicura che i prodotti suddetti soddisfano le clausole della direttiva del Consiglio 98/79/ec (Direttiva IVD) e recepite nell'ordinamento nazionale.

Nosotros, QUIDEL Corporation aseguramos y declaramos bajo nuestra única responsabilidad, que los productos arriba mencionados cumplen los requisitos de la directiva del Consejo 98/79/EC (directiva IVD) transformado en la normativa nacional.

Nós, QUIDEL Corporation, asseguramos e declaramos sob nossa única responsabilidade, que os produtos acima mencionados cumprem os requisitos da Directiva do Conselho 98/79/EC (Directiva DIV), transpostas para os regulamentos nacionais.

Wij, QUIDEL Corporation, als enige verantwoordelijk, verklaren en verzekeren hierbij dat de bovengenoemde producten voldoen aan de eisen gesteld in de EG Richtlijn 98/79/EC (IVD richtlijn), zoals omgezet in nationale regelgeving.

My, QUIDEL Corporation zapewniamy i deklarujemy na własną odpowiedzialność, że wymienione wyżej produkty spełniają przepisy dyrektywy Rady 98/79 / WE (dyrektywy IVD) transponowane do przepisów krajowych.

Classification: Article 9(1) of EC Council Directive 98/79/EC on *in vitro* diagnostic devices
Conformity assessment route: Annex III (IVDD self-affixed)

EC REP

MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 26th day of February, 2019

Karl E. Luke, PhD, Director, Clinical and Regulatory Affairs

Quidel Corporation
2005 East State Street, Suite 100
Athens, OH 45701 USA
+1(858) 552-1100 quidel.com

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