



**KONFORMITÄTSERKLÄRUNG / DECLARATION DE CONFORMITE
DECLARATION OF CONFORMITY / DICHIARAZIONE DI CONFORMITA**

Manufacturer:

Shijiazhuang Hipro Biotechnology Co.,
Ltd.

No.3 Building,Block C,Fangyi Tech.
Park, No. 313Zhujiaqadao
Street,Shijiazhuang,050035 China

whose single Authorized Representative:

Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd, 2595AA, The
Hague, Netherlands

Wir erklären in alleiniger Verantwortung, dass / Nous déclarons sous notre propre responsabilité que /Dichiariamo sotto nostra responsabilità che / We declare under our sole responsibility that

POCT ImmunoAssay System (Sampling and Sample Injector Units)

Enzyme Rate Method:

Adenosine deaminase Test Kit
Homocysteine Test Kit

Nephelometry immunoassay Method:

Alpha-Fetoprotein Test Kit
Antistreptolysin O Test Kit
Anti-Cyclic Peptide Containing Citrulline Antibody Test Kit
C-reactive Test Kit
Cardiac Troponin I Test Kit
Cystatin C Test Kit
D-Dimer Test Kit
Glycosylated Hemoglobin (HbA1c) Test Kits
Heart Fatty Acid binding Protein Test Kit
High sensitivity C-reactive protein Test Kit
Microalbuminuric Test Kit
Myohemoglobin Test Kit
Neutrophil Gelatinase-Associated Lipocalin Test Kit
Rheumatoid Factor Test Kit
25-OH-VD Test Kit
Carcinoembryonic antigen Test Kit

**das Medizinprodukt
le dispositif médical
the medical device
il dispositivo medico**

Rate Scattering Turbidimetric Method:

Immunoglobulin A Test Kit
Immunoglobulin E Test Kit
Immunoglobulin G Test Kit
Immunoglobulin M Test Kit
Lipoprotein(a) Test Kit
Lipoprotein Phospholipase A2 Test Kit
Prealbumin Test Kit
Procalcitonin Test Kit
Propepsin I Test Kit
Propepsin II Test Kit
Retinol binding protein Test Kit
Serum amyloid A Test Kit
Transferrin Test Kit
Ferritin Test Kit
Alpha-1-microglobulin Test Kit
Beta-2-microglobulin Test Kit
Heart Fatty Acid binding Protein Test Kit

Immune Suppression Method:

Creatine Kinase Isoenzyme MB Test Kit

Immune Fluorescence Detection Method:

Amino-terminal pro-brain natriuretic peptide Test Kits
Human chorionic gonadotrophin Test Kit

Bezeichnung, Typ oder Modell, Chargen- oder Seriennummer, ev. Herkunft und Stückzahl Nom, type ou modèle, 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

der Klasse / de la classe / della classe / of class

Other IVD Devices

Nach Richtlinie 98/79/EG / selon directive 98/79/CE / secondo direttiva 98/79/CE / according to direct. 98/79/EC.

allen Anforderungen der Medizinprodukte-Richtlinie 98/79/EG entspricht, die anwendbar sind/ remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/CE) qui le concernent / soddisfa tutte le disposizioni della direttiva 98/79/CE che lo riguardano /meets all the provisions of the directive 98/79/EC which apply to it.

Angewandte harmonisierte Normen,
nationale Normen oder andere
normative Dokumente

Normes harmonisées, normes
nationales et autres documents
normatifs appliqués

Norme armonizzate o nazionali
applicate,altri documenti normativi
applicati

Applied harmonised standards, national
standards or other normative
documents

Konformitätsbewertungsverfahren

Procédure d'évaluation de la conformité

Procedimento di valutazione della
conformità

Conformity assessment procedure

IVDD 98/79/EC, Annex III

Shijiazhuang 2021.02.27

Ort, Datum / Lieu, date / Luogo, data / Place, date

石家庄禾柏生物技术股份有限公司

Shijiazhuang Hebo Biotechnology Co., Ltd.

Name und Funktion / Nom et fonction

Nome e funzione / Name and function