



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

*Manufacturer:*

Shijiazhuang Hipro Biotechnology Co.,  
Ltd.  
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*whose single Authorized Representative:*

Lotus NL B.V.

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**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 FactorTest Kit  
25-OH-VD Test Kit  
Carcinoembryonic antigen Test Kit

**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 choionic gonadotrophin Test Kit

das Medizinprodukt  
le dispositif médical  
the medical device  
il dispositivo medico

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