



**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. 313Zhujiangdadao  
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 HEPPO-BIO Technology Co., Ltd.  
Name und Funktion / Nom et fonction  
/Nome e funzione / Name and function