# DECLARATION OF CONFORMITY

**MANUFACTURER** : Bioneer Corporation
8-11, Munpyeongseo-ro
Daedeok-gu, Daejeon, 34302, Republic of Korea

**EUROPEAN REPRESENTATIVE** EC REP : MT Promedt Consulting GmbH
Altenhofstr. 80
D-66386 St. Ingbert, Germany

**PRODUCT NAME** : *ExiPrep*™ Dx Viral DNA/RNA Kit

**CATALOG NO.** REF : K-4471

**CLASSIFICATION** : Others
(Neither Listed in Annex II of IVDD, nor self-testing device)

**CONFORMITY ASSESSMENT ROUTE** : IVDD ANNEX III

***We herewith declare that the above mentioned products meet the provisions of the council directive 98/79/EC for in vitro medical devices. All supporting documentation is retained under the premises of the manufacturer. Declaration of Conformity is issued under the sole responsibility of the manufacturer.***

**STANDARDS APPLIED** : EN ISO 13485: 2016, EN 15223-1:2016, EN ISO 15193:2009, EN 13612:2002, EN ISO 23640:2015, EN 14136:2004, EN ISO 14971:2012, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13975:2003, EN ISO 15194:2009, EN 13641:2002

**PLACE, DATE OF ISSUE** Daejeon, Republic of Korea

**SIGNATURE** Han Oh Park **DATE** 2018-12-10

HAN-OH PARK, CEO

CE