

DECLARATION OF CONFORMITY

MANUFACTURER : Bioneer Corporation
49-3 Munpyeong-dong
Daedeok-gu, Daejeon, 306-220
Republic of Korea

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

PRODUCT NAME : AccuPower® Enterovirus Quantitative PCR kit
CATALOG NO. : ENT-1111, ENT -1112, ENT -1113

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

CONFORMITY ASSESSMENT ROUTE : IVDD ANNEX III APPLIED

We herewith declare that the above mentioned products meet the provisions of the council directive 98/79/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

STANDARDS APPLIED: ISO13485:2003, EN375:2001, EN13640:2002, EN14971:2007,
EN12286:1999, EN 13612:2002, EN980:2008, EN13975:2003,
EN14136:2004, EN ISO17511:2003, EN12287:1999,
EN13641:2002

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SIGNATURE :



HAN-OH PARK, CEO