

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*[®] CP Real-Time PCR kit
CATALOG NO. : CPN-1111, CPN-1112, CPN-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

PLACE, DATE OF ISSUE : Daejeon, Republic of Korea, January, 19, 2009

SIGNATURE :



HAN-OH PARK, CEO