

DECLARATION OF CONFORMITY

MANUFACTURER



: Bioneer Corporation
8-11 Munpyeong Seo ro
Daedeok-gu, Daejeon, 34302
Republic of Korea

EUROPEAN
REPRESENTATIVE



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

PRODUCT

: *AccuPower*[®] ZIKV (DENV, CHIKV) Multiplex Real-Time
RT-PCR Kit

CATALOG NO.

: ZIK-1111

EDMA code/ Term

: 15 04 40 90 00 / Other Virology - NA Reagents

CLASSIFICATION

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

CONFORMITY

: IVDD ANNEX III

ASSESSMENT ROUTE

We here with declare that the above mentioned products meet the provisions of the council directive 98/79/EC for In Vitro diagnostic medical device. All supporting documentation is retained under the premises of the manufacturer.

STANDARDS APPLIED: IVD directive 98/79/EC, EN ISO13485:2012, EN ISO 15193:2009, EN13612:2002, EN 13640:2002, EN 14136:2004, EN ISO 14971:2012, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13975:2003, EN ISO 15194:2009, EN 13641:2002, EN 980:2008, EN 62366:2008

PLACE, DATE OF ISSUE : Daejeon, Republic of Korea, FEBRUARY 11, 2016

SIGNATURE

: 

HAN-OH PARK, Ph.D.

