CE

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 : *ExiPrep*™16 Dx,
Fully Automated Nucleic Acid Extraction System

CATALOG NO. (REF) A-5050

EDMA Code/Term : 26 09 Other, Other Clinical Instrument

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 diagnostic medical device. All supporting documentation is retained under the premises of the manufacturer.

STANDARDS APPLIED : EN 61010-1:2010, EN 61010-2-081:2015,
EN 61010-2-010:2014, EN61010-2-101:2015,
EN61326-1:2013, EN61326-2-6:2013
EN 61000-4-2: 2009, EN 61000-4-3:2006/A1:2008/A2:2010,
EN 61000-4-4:2012, EN 61000-4-5:2014,
EN 61000-4-6:2014, EN 61000-4-11:2004
EN ISO 14971:2012, EN ISO 13485:2016, EN 62304:2006,
EN 62366;2008, EN ISO15223-1;2016, EN ISO 18113-1:2011,
EN ISO 18113-3:2011

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