Declaration of Conformity

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

EUROPEAN REPRESENTATIVE: Medical Technology PROMEDT Consulting GmbH
Altenhofstrasse 80, D-66386 St.Ingbert, Germany

PRODUCT: Exicycler™ 96 Real-Time Quantitative Thermal Block Cat. # A-2060

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

CONFORMITY ASSESSMENT ROUTE: IVDD ANNEX APPLIED

WE HEREBITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:
- IEC61010-1:2001,
- IEC61010-2-101:2002,
- IEC61010-2-081:2001,
- IEC61010-2-010:2003,
- EN610326:2003,
- EN60601-1-2:2001

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SIGNATURE: Han Oh Park, Ph.D.
CEO, Bioneer Corporation