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CE

Declaration of Conformity

Manufacturers Name:	**BIONEER Corporation**
Manufacturers Address:	8-11, Munpyeongseo-ro Daedeok-gu, Daejeon, 34302, Republic of Korea
SRN(Single Registration Number):	
Authorized Representative :	MT Promedt Consulting GmbH Altenhofstr. 80, 66386 St. Ingbert, Germany
Basic UDI-DI :	880953707K3033M76
Device Type:	Nucleic acid Extraction Kit
Product Name:	*AccuPrep*® Dx Viral RNA Extraction Kit
Catalogue Number:	K-3033M
Classification:	Class A (Rule 5(a), IVDR Annex VIII),
Conformity assessment route:	BIONEER uses the following assessment procedures for the CE marking of the products according the *Regulation (EU) IVDR 2017/746 for in vitro diagnostic medical devices* Annex IV and Article 48(10)
Reference:	IVDR (EC) 2017/746, EN ISO 15193:2009, EN 14136:2004, EN ISO 17511:2003, EN ISO 15194:2009, EN ISO 13485:2016, EN13612:2002, EN13641:2002, EN13975:2003, EN ISO14971:2012, EN ISO 15223-1:2016, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 23640:2015, IEC 62366-1:2015/AMD1:2020

This declaration of conformity is issued under the sole responsibility of BIONEER. We hereby declare that the in vitro medical device(s) specified above meet the provision of the Regulation (EU) IVDR 2017/746 for in vitro diagnostic medical devices.
All supporting documentation is retained at the premises of the manufacturer.

PLACE, DATE OF ISSUE : ***Daejeon, Republic of Korea, 2022-05-19***

SIGNATURE :

HAN-OH PARK, CEO