

## EC Declaration of Conformity

We herewith declare that the under-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.

<b>Company Name</b>	NanoEnTek, Inc.
<b>Manufacturer</b>	12F, 5, Digital-ro 26-gil, Guro-gu, Seoul, 152-740, Korea
<b>Manufacturing site</b>	851-14, Seohae-ro, Paltan-myeon, Hwaseong-si, Gyeonggi-do, 445-917, Korea
<b>EC Representative</b>	MT Promedt Consulting GmbH Altenhofstrasse 80, 66386 St. Ingbert, Germany
<b>Product Name</b>	Rapid Quantitative Assay for CK-MB, Myoglobin and Troponin I
<b>Product Category (ies)</b>	Reagents, Rapid Tests, Cardiac Markers
<b>Model Name (Catalogue number)</b>	FREND™ Cardiac Triple (FRCT 025)
<b>EDMA Codes</b>	12 70 13 01 00 Creatine Kinase – MB mass – Rapid Test, CK-MB 12 70 13 02 00 Myoglobin – Rapid Test, MYO 12 70 13 03 00 Troponin I/T – Rapid Test, cTnI, cTnT
<b>Classification</b>	Categorized as “Others” according to Annex III, IVDD 98/79/EC
<b>Conformity Assessment Route</b>	IVDD Annex III EC Declaration of Conformity
<b>Harmonized Standards</b>	EN ISO 13485:2012, EN ISO 14971:2012, EN ISO 17511:2003, EN ISO 18113-2:2011, EN 980:2008, ISO 7000:2012 EN 13612:2002, EN 13640:2002, EN 13641:2002, EN 13975:2003
<b>Start date of CE marking</b>	September 1, 2014(CK-MB and Myoglobin), September 26, 2014(TnI)
<b>Notified Body</b>	Not applicable



Signature:

Hur, Daesung / Quality Management Representative