

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.

Company Name	NanoEnTek, Inc.
Manufacturer	12F, 5, Digital-ro 26-gil, Guro-gu, Seoul, 152-740, Korea
Manufacturing site	851-14, Seohae-ro, Paltan-myeon, Hwaseong-si, Gyeonggi-do, 445-917, Korea
EC Representative	MT Promedt Consulting GmbH Altenhofstrasse 80, 66386 St. Ingbert, Germany
Product Name	Rapid Quantitative Assay for CK-MB, Myoglobin and Troponin I
Product Category (ies)	Reagents, Rapid Tests, Cardiac Markers
Model Name (Catalogue number)	FREND™ Cardiac Triple (FRCT 025)
EDMA Codes	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
Classification	Categorized as “Others” according to Annex III, IVDD 98/79/EC
Conformity Assessment Route	IVDD Annex III EC Declaration of Conformity
Harmonized Standards	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
Start date of CE marking	September 1, 2014(CK-MB and Myoglobin), September 26, 2014(TnI)
Notified Body	Not applicable



Signature:

Hur, Daesung / Quality Management Representative