

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.

Manufacturer	NanoEnTek, Inc.
Address	851-14, Seohae-ro, Paltan-myeon, Hwaseong-si, Gyeonggi-do, 18531, Korea 12F, 5, Digital-ro 26-gil, Guro-gu, Seoul, 08389, Korea
EC Representative	MT Promedt Consulting GmbH Altenhofstrasse 80, 66386 St. Ingbert, Germany
Product Name	Rapid Quantitative Assay for Procalcitonin
Product Category (ies)	Individual and Specified Hormones/Proteins
Model Name (Catalogue number)	FREND™ PCT (FRPC 025)
EDMA Codes	12 06 90 16 00 Procalcitonin
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	January 01, 2016
Notified Body	Not applicable



Signature: _____

Kyuhoo Kim

Kim, Kyuhoo / Regulatory Affairs Manager