

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. 851-14, Seohae-ro, Paltan-myeon, Hwaseong-si, Gyeonggi-do, 18531, Korea
Facility(ies)	NanoEnTek Inc. 851-14, Seohae-ro, Paltan-myeon, Hwaseong-si, Gyeonggi-do, 18531, Korea
EC Representative	NanoEnTek Inc. 12F, 5, Digital-ro 26-gil, Guro-gu, Seoul, 08389, Korea
Product Name(Model name)	MT Promedt Consulting GmbH Altenhofstrasse 80, 66386 St. Ingbert, Germany
Product Category (ies)	FREND™ System
Catalogue number	Instruments, Immunochemistry instruments, Immunoassay analyser
EDMA Codes	F10
Classification	22 03 01 Manual I.A. Instruments/Readers
Conformity Assessment Route	Categorized as "Others" according to Annex III, IVDD 98/79/EC
Harmonized Standards	IVDD Annex III Declaration of Conformity
Start Date of CE-marking	EN ISO 13485:2012, EN ISO 14971:2012, EN 980:2008, ISO 7000:2012, EN ISO 17511:2003, EN ISO 18113-3:2011, EN 13612:2002, EN 13641:2002, EN 13975:2003, EN 61010-1:2010, EN 61010-2-081:2001, EN 61010-2-101:2002, EN 61326-2-6:2006, EN 62304:2006
Notified Body	October 20, 2008
	Not applicable



Signature: _____



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