NanoEnTek

Revolutionary Wave for Human Wellbeing

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 NanoEnTek Inc. 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(Model name)	FREND™ System
Product Category (ies)	Instruments, Immunochemistry instruments, Immunoassay analyser
Catalogue number	F10
EDMA Codes	22 03 01 Manual I.A. Instruments/Readers
Classification	Categorized as "Others" according to Annex Ⅲ, IVDD 98/79/EC
Conformity Assessment Route	IVDD Annex Ⅲ Declaration of Conformity
Harmonized Standards	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
Start Date of CE-marking	October 20, 2008
Notified Body	Not applicable

CE

Signature: Shin mt Sun

Shin, Misun / Regulatory Affairs Manager

REPUBLICA MOLDOVA, mun. CHIȘINĂU, I.C.S. "DIAMEDIX IMPEX" S.R.L. PENTRU FACTURI I.C.S. "DIAMEDIX IMPEX" S.R.L. IDNO 1012600019967 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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