NanoEnTek
Revolutionary Wave for Human Welfare

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	Blood Counting Chambers (Disposable plastic microchips)
Product Category (ies)	Instruments, Haemetology instruments, Blood cell counter
Model Name (Catalogue number)	C-Chip™ (DHC-N01, DHC-F01, DHC-B02, DHC-B01, DHC-M01)
EDMA Codes	23 02 01 No Differential Blood Cell Counter
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 ISO 17511:2003, EN ISO 18113-2:2011, EN 980:2008, EN 13612:2002, EN 13640:2002, EN 13641:2002, EN 13975:2003,
Start Date of CE-marking	June 01, 2010
Notified Body	Not applicable

CE

Signature: Kyuho Kim

Kim, Kyuho / Regulatory Affairs Manager

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