

## EC Declaration of Conformity

We herewith declare that the under-mentioned products meet the provisions of the own standard operating procedure. All supporting documentation is retained under the premises of the manufacturer and manufacturer is exclusively responsible for the declaration of conformity.

<b>Manufacturer</b>	NanoEnTek Inc. 851-14, Seohae-ro, Paltan-myeon, Hwaseong-si, Gyeonggi-do, 18531, Korea
<b>Facility (ies)</b>	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
<b>EC Representative</b>	MT Promedt Consulting GmbH Altenhofstrasse 80, 66386, St. Ingbert, Germany
<b>Product Category (ies)</b>	Instruments/Consumables, Haemato./Heamostas./ ImmunoHaemato./Histol./Cytol.
<b>Product Name</b>	Disposable plastic microchip (Cell/Blood Counting Chamber)
<b>Model Name (Catalogue number)</b>	C-Chip (DHC-N01, DHC-B01, DHC-B02, DHC-F01, DHC-M01) 2-Chip for ODM
<b>EDMA Codes</b>	23 01 Cell Counting (CC) also (23 02 01)
<b>Harmonized Standards</b>	EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-3:2011, EN 13612:2002, EN 23640:2015, EN 13641:2002, EN 13975:2003
<b>Start date of CE marking</b>	June 01, 2010
<b>Notified Body</b>	Not applicable



Signature: \_\_\_\_\_

*Kyuho Kim*

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