

EC Declaration of Conformity

We, NanoEntek, herewith declare that the under-mentioned products meet the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

All supporting documentation is retained under the premises of the manufacturer and manufacturer is exclusively responsible for the declaration of conformity.

Manufacturer	NanoEntek, Inc. (SRN: KR-MF-000021903) 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 (SRN: DE-AR-000000085) Altenhofstrasse 80, 66386 St. Ingbert, Germany
Product Category (ies)	Instruments/Consumables, Haemato./Heamostas./ ImmunoHaemato./Histol./Cytol.
Product Group	Disposable Plastic Microchips; Blood Counting Chambers; Haemocytometer
Product Name	C-Chip
Model Name (Catalogue number)	[2 channel model] DHC-N01 (DHC-N01), DHC-B01 (DHC-B01), DHC-B02 (DHC-B02) DHC-F01 (DHC-F01), DHC-M01 (DHC-M01) [4 channel model] DHC-N04 (DHC-N04), DHC-B04 (DHC-B04), DHC-F04 (DHC-F04) DHC-N0420(DHC-N0420), DHC-B0420(DHC-B0420), DHC-F0420(DHC-F0420)
Basic UDI DI Code	(DHC-N01) 8809317540511DHC-N01Q2 (DHC-B01) 8809317540573DHC-B01TN (DHC-B02) 8809317540580DHC-B02SN (DHC-F01) 8809317540597DHC-F01Y4 (DHC-M01) 8809317540603DHC-M01R9 (DHC-N04,DHC-N0420) 8809317540665DHC-N04X4 (DHC-B04,DHC-B0420) 8809317540689DHC-B04Z2 (DHC-F04,DHC-F0420) 8809317540702DHC-F04QN
Classification	Categorized as "Class A" according to Annex VIII, Regulation (EU) 2017/746
Conformity Assessment Procedure	According to Annex IX and the GSPR of Annex I, Regulation (EU) 2017/746
EDMA Code	23 02 01 No Differential Blood Cell Counter (23 01 Cell counting (CC))
GMDN Code	43673 Microscope counting chamber IVD
EMDN Code	W050301029099 SAMPLES ANALYSES, PLASTIC CONTAINERS - OTHER

Harmonized Standards	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
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Start Date of CE-marking	June 01, 2010
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Notified Body	Not applicable
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Signature:



Jongsung Lee / Regulatory Affairs Team Leader