NanoEntek, Inc.
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REACH / SVHC Declaration of Conformity

Declaration regarding Substances of Very High Concern (SVHC) under Regulation (EC) No 1907/2006 (REACH)

Document No.: NEET-REACH-DHC-N01 **Date of issue:** 2026-06-29

Manufacturer	NanoEntek, Inc.
Manufacturing site	851-14 Seohae-ro, Paltan-myeon, Hwaseong-si, Gyeonggi-do, 18531, Korea
EU Authorised Rep.	MT Promedt Consulting GmbH, Ernst-Heckel-Straße 7, 66386 St. Ingbert, Germany
Product name	C-Chip — Disposable Plastic Hemocytometer
Model / Catalogue No.	[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	880931754C-ChipH5
Material of construction	Poly(methyl methacrylate) — PMMA (CAS No. 9011-14-7)
Regulatory status	Class A in vitro diagnostic medical device, Regulation (EU) 2017/746

Declaration

1. NanoEntek, Inc. confirms that the above-referenced product qualifies as an *article* within the meaning of Article 3(3) of Regulation (EC) No 1907/2006 (REACH). Under normal and reasonably foreseeable conditions of use, the product does not intentionally release any substance; accordingly, registration under Article 7(1) of REACH is not applicable.

2. The product is manufactured from poly(methyl methacrylate) (PMMA, CAS No. 9011-14-7). Based on the composition of this material and the information provided by our raw-material supplier (Safety Data Sheet), PMMA is not a Substance of Very High Concern.

3. To the best of our knowledge, and based on the above material composition and supplier information, the product does **not** contain any Substance of Very High Concern (SVHC) on the REACH Candidate List in a concentration exceeding 0.1 % by weight (w/w).

4. This declaration refers to the REACH Candidate List of SVHC as last updated by the European Chemicals Agency (ECHA) on 4 February 2026 (253 entries). As the Candidate List is updated periodically, this declaration will be reviewed and, where necessary, revised upon any subsequent update of the list or any change in product composition.

5. As no SVHC is present above 0.1 % w/w, no information obligation toward recipients under Article 33 of REACH arises for this product.

This declaration is issued on the basis of current knowledge and supplier information available at the date of issue. It is provided for information purposes and does not constitute a warranty in the legal sense.

Issued by

Name / Title:	JongSung LEE / RA Team Leader
Signature:	
Date:	2026 - 06 - 29