



Product Service

Certificate

No. Q5 064393 0007 Rev. 01

Holder of Certificate: **NanoEntek, Inc.**
851-14, Seohae-ro, Paltan-myeon
Hwaseong-si, Gyeonggi-do 18531
REPUBLIC OF KOREA

Certification Mark:



Scope of Certificate: **Design, Development, Production and Distribution of In Vitro Diagnostic Reagents Instruments - Rapid Quantitative Assay Chip, Disposable Plastic Microchips, Fluorescence measuring Instrument, Auto residual Leukocyte Counter and Accessories, Point-of-care testing(POCT) Product, Cell Counter and Accessories**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 064393 0007 Rev. 01

Report No.: 74961431

Valid from: 2022-04-01
Valid until: 2025-03-31

Date, 2022-03-30

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 064393 0007 Rev. 01

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): NanoEntek, Inc.
12F, 5, Digital-ro 26-gil, Guro-gu, Seoul 08389, REPUBLIC OF
KOREA

Design and Development of In vitro Diagnostic Reagents
Instruments - Rapid Quantitative Assay Chip, Disposable Plastic
Microchips, Fluorescence measuring Instrument, Auto residual
Leukocyte Counter and Accessories, Point-of care(POCT)
Product, Cell Counter and Accessories

NanoEntek, Inc.
851-14, Seohae-ro, Paltan-myeon, Hwaseong-si, Gyeonggi-do
18531, REPUBLIC OF KOREA

Production and Distribution of In vitro Diagnostic Reagents
Instruments – Rapid Quantitative Assay Chip, Disposable Plastic
Microchips, Fluorescence measuring Instrument, Auto residual
Leukocyte Counter and Accessories, Point-of-care (POCT)
Product, Cell Counter and Accessories

./.