

# Certificate of Reference Material

## (Product Information Sheet)

· **Product Name** ZDEC-SPU sheet for implantation tests in subcutaneous tissue

· **Catalog No.** KR-P-CTS 1015E

· **Lot No.** RM-P-22

· **Product Information**  
ZDEC-SPU sheet, t 0.5 mm, 100 mm x 150 mm  
(ZDEC contents 0.25 wt %)

· **Packaging Unit** 1 sheet/package

· **Certified Date** 2023. 10. 26

· **Expiry Date** 2024. 04. 25

· **Method** ISO 10993-6 & ISO 10993-5

· **Hazard**



KEMIDAS Co., Ltd has produced and verified the Reference Material by the following quality management system; ISO 9001 Quality Management System Registered, ISO 17034 (ACC No. KRMPs-015) Accredited.

· **Intended Use** This RM is intended for use as a negative response in implantation tests in subcutaneous tissue (laboratory use only)

· **Storage** Store at a cool and dark place (< 25 °C)

· **Homogeneity** The RM was processed according to the in-house procedure KLQP-18-F01 and is determined to be homogeneous.

· **Stability** It is determined to be stable until the expiration date specified above if the RM is handled and stored in accordance with the instructions given in this certificate. This stability is nullified if the RM is opened. The stability was confirmed by the stability evaluation report (KRQP-04-F01).

### · Certified Value and Uncertainty

Material	Property	Certified Value	Uncertainty
ZDEC-SPU	Cytotoxicity	Grade 4	-
	Implantation	Moderate reaction	-

\* Shelf life of standard materials may vary depending on storage conditions.

\* The non-sterilized RM is necessary to be sterilized in an autoclave (120 °C, 15 min) or with ethylene oxide gas (40 °C, 6 hrs). When autoclave sterilization is applied, excessive condition such as higher temperature and longer time should be avoided. When EO gas sterilization is done, a sufficient degassing of RM is recommended. The RM should be sterilized only one time.

### · Approved by

Technical manager : Yoon, In-Seon

**Kemidas** 케미다스



The above reference material certificate is the accredited result of RM to KS A ISO 17034 by Korea Laboratory Accreditation Scheme.

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