

## Certificate of Analysis

| 1. Commodity          |                                       | Accufuser                                                          |      |            |          |                  |
|-----------------------|---------------------------------------|--------------------------------------------------------------------|------|------------|----------|------------------|
| 2. Model No.          |                                       | C0100L                                                             |      |            |          |                  |
| 3. Lot No.            |                                       | 1B9K131                                                            |      |            |          |                  |
| 4. Manufactured Date  |                                       | 2019-11-21                                                         |      |            |          |                  |
| 5. Sterilization Date |                                       | 2019-11-22                                                         |      | Batch No.  | 생멸 KG17  |                  |
| 6. Issue Date         |                                       | 2019-12-12                                                         |      |            |          |                  |
| Item                  |                                       | Limits                                                             |      | Results    | Decision | Relevant SOP' s  |
| Physical Test         | Appearance                            | No Defect                                                          |      | No Defect  | Pass     | WYM-I090-P03     |
|                       | Flow rate                             | 10.0ml/hr                                                          | ±10% | -7.80%     | Pass     | WYM-I090-05      |
|                       | Basal/Bolus Function                  |                                                                    |      |            |          | WYM-I090-06      |
|                       | Air Tightness                         | No Bubble Appearance                                               |      | Normal     | Pass     | WYM-I090-07      |
|                       | Adhesion Strength                     | Over 2.0kgf                                                        |      | Pass       | Pass     | WYM-I090-04      |
| Biological Test       | Acute Systemic Toxicity               | No Defect within 7days                                             |      | MTK-004825 | Pass     | ISO10993-11      |
|                       | Pyrogen                               | LAL reagent                                                        |      | -Reaction  | Pass     | WYM-I090-08      |
| Chemical Test         | Appearance                            | Colorless, Transparent                                             |      | Normal     | Pass     | WYM-I090-10      |
|                       | pH                                    | NMT 1.5                                                            |      | 0.79       | Pass     |                  |
|                       | KMnO <sub>4</sub> Reducing Substances | NMT 2.0ml                                                          |      | 0.50       | Pass     |                  |
|                       | Heavy Metals                          | The sample solution should not be darker than the control solution |      | MTK-004958 | Pass     | K.P General Test |
|                       | Residue on Evaporation                | NMT 1.0mg                                                          |      | MTK-004958 | Pass     |                  |
| Sterility Test        | Biological Indicator                  | Negative Growth within 7days                                       |      | Negative   | Pass     | WYM-I090-02      |
|                       | Chemical Indicator                    | Color Change                                                       |      | Change     | Pass     |                  |

Issued by  
Q.A Manager

C. H. Kim 