

MARS Bar Tubing Set (BRB02) – Certificate of Compliance

February 2025

This document certifies the product meets the following statements

1. **Cytotoxicity Test Results:** Compliance of MARS Bar Tubing Set with ISO 10993-5:2009 standards and no cytotoxicity to L-929 cells.
2. **Transportation Study Test Results:** MARS Bar Tubing Set passed transportation stress tests under ASTM D4169 DC13 standards.
3. **Endotoxin Test Results:** The bacterial endotoxin content of the test article was found to be less than 2.5 EU/device, confirming safety under test conditions.
4. **1-Year Sterility Test Results:** The test items included accelerated aging test, visual inspection, vacuum leak test, dye penetration test, microbial barrier properties test, seal strength test, and burst test. MARS Bar Tubing Set passed requirements in ISO 11607.
5. **1-Year Accelerated Aging Test Results:** MARS Bar Tubing Set met ISO 11737-2:2019 standards, and no microbial growth was observed in culture media with the test article.
6. **PTT Test Results:** The in vitro test assessed partial thromboplastin time. The results showed that there was no significant difference in the PTT between the MARS Bar Tubing Set test article and the blank control or negative control.
7. **In Vitro Hemolytic Test Results:** The hemocompatibility test evaluated the effect of the MARS Bar Tubing Set on hemolytic properties, confirming compliance with standard criteria. Under the conditions of this study, the hemolysis grade of the MARS Bar Tubing Set sample was nonhemolytic by both the direct method and the extraction method.
8. **Acute Systemic Toxicity Results:** Tested on mice, the extract from MARS Bar Tubing Set caused no acute systemic toxicity under the conditions of the experiment. No animals were found to have abnormal clinical symptoms.
9. **In Vitro Test Results:** In vitro mammalian cell gene mutation test was conducted per established standards, and verified MARS Bar Tubing Set in compliance with ISO 10993.
10. **Intracutaneous Reactivity Test Results:** The test determined the potential for intracutaneous reactivity in rabbits with extract from MARS Bar Tubing Set. No adverse skin reactions found.
11. **Barrier Seal Test Results:** MARS Bar Tubing Set packaging integrity is in compliance with ISO 11607.
12. **Pyrogen Test Results:** The intravenous injection study in rabbits to determine pyrogenic response. Under the conditions of this study, the MARS Bar Tubing Set extract met the requirements for the absence of pyrogens.
13. **Sterility Test Results:** MARS Bar Tubing Set is compliant with ISO 11737-2:2019 standards with no microbial growth was detected, confirming sterility.
14. **Animal Content:** MARS Bar Tubing Set does not contain materials of animal or insect origin.