**Biocompatibility Test Matrix**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Device Categories | | Initial Evaluation | | | | | | | | Supplemental Evaluation | |
| Nature Body Contact | Contact Duration | Cytotoxicity | Sensitization | Irritation or Intracutaneous reactivity | Systemic Toxicity (Acute) Pyrogenicity | Subchronic Toxicity | Genetotoxicity | Implantation | Hemocompatibility | Chronic Toxicity | Cytotoxicity |
| Surface Device | Skin | A  B  C | \*  \*  \* | \*  \*  \* | \*  \*  \* |  |  |  |  |  |  |  |
| Mucosal Membrane | A  B  C | \*  \*  \* | \*  \*  \* | \*  \*  \* | ®  ® | ®  \* | \* | ®  ® |  | ® |  |
| Breached/Compromised surface | A  B  C | \*  \*  \* | \*  \*  \* | \*  \*  \* | ®  ®  ® | ®  \* | \* | ®  ® |  | ® |  |
| External Communicating Devices | Blood Path Indirect | A  B  C | \*  \*  \* | \*  \*  \* | \*  \*  ® | \*  \*  \* | ®  \* | \* | ® | \*  \*  \* | \* | \* |
| Tissue/Bone dentin Communicating | A  B  C | \*  \*  \* | \*  \*  \* | \*  ®  ® | ®  ®  ® | ®  ® | \*  \* | \*  \* |  | ® | \* |
| Circulating Blood | A  B  C | \*  \*  \* | \*  \*  \* | \*  \*  \* | \*  \*  \* | ®  \* | ®  \*  \* | ®  ® | \*  \*  \* | \* | \* |
| Implant Devices | Bone/Tissue | A  B  C | \*  \*  \* | \*  \*  \* | \*  ®  ® | ®  ®  ® | ®  ® | \*  \* | \*  \* |  | \* | \* |
| Blood | A  B  C | \*  \*  \* | \*  \*  \* | \*  \*  \* | \*  \*  \* | ®  \* | \*  \* | \*  \*  \* | \*  \*  \* | \* | \* |
| A: Limited Exposure (<24 hrs) , B: Prolonged Exposure (24 hrs to 30 days), C: Permanent Contact (> 30 days)  \* FDA/ ISO Evaluation Test  ® Additional Evaluation test | | | | | | | | | | | | |

