**Biocompatibility Test Matrix**

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| --- | --- | --- | --- |
|  | 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 | ABC | \*\*\* | \*\*\* | \*\*\* |  |  |  |  |  |  |  |
| Mucosal Membrane | ABC | \*\*\* | \*\*\* | \*\*\* | ®® | ®\* | \* | ®® |  | ® |  |
| Breached/Compromised surface | ABC | \*\*\* | \*\*\* | \*\*\* | ®®® | ®\* | \* | ®® |  | ® |  |
| External Communicating Devices | Blood Path Indirect | ABC | \*\*\* | \*\*\* | \*\*® | \*\*\* | ®\* | \* | ® | \*\*\* | \* | \* |
| Tissue/Bone dentin Communicating | ABC | \*\*\* | \*\*\* | \*®® | ®®® | ®® | \*\* | \*\* |  | ® | \* |
| Circulating Blood | ABC | \*\*\* | \*\*\* | \*\*\* | \*\*\* | ®\* | ®\*\* | ®® | \*\*\* | \* | \* |
| Implant Devices | Bone/Tissue | ABC | \*\*\* | \*\*\* | \*®® | ®®® | ®® | \*\* | \*\* |  | \* | \* |
| Blood | ABC | \*\*\* | \*\*\* | \*\*\* | \*\*\* | ®\* | \*\* | \*\*\* | \*\*\* | \* | \* |
| 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  |

