

Biomedical Device Standard Waiver Template

Device Information

Device Name	<input type="text"/>
Model Number	<input type="text"/>
Manufacturer	<input type="text"/>
Serial Number	<input type="text"/>

Waiver Request Details

Relevant Standards to be Waived	<input type="text"/>	Reason for Waiver Request
<input type="text"/>	<input type="text"/>	
Summary of Risk Assessment		

Mitigation Measures

<input type="text"/>	<input type="text"/>
Describe Mitigation Measures	

Additional Comments

<input type="text"/>

Approval

Requested By	<input type="text"/>
Date	<input type="text"/>
Approved By	<input type="text"/>
Date	<input type="text"/>

