

Medical Device Engineering Change Request (ECR) Form

General Information

ECR Number

Date

Requested By

Department

Device/Product Name

Model/Part Number

Description of Change

Type of Change

Change Description

Reason for Change

Proposed Implementation Date

Affected Documents/Parts

Impact Assessment

Regulatory Impact

Quality Impact

Other Potential Impacts

Review & Approval

Initiator Date

Engineering Date

Quality Date

Regulatory Date

Management Date
