

PREPARING RISK MANAGEMENT REPORT

GLOBAL MEDICAL DEVICE CONSULTING

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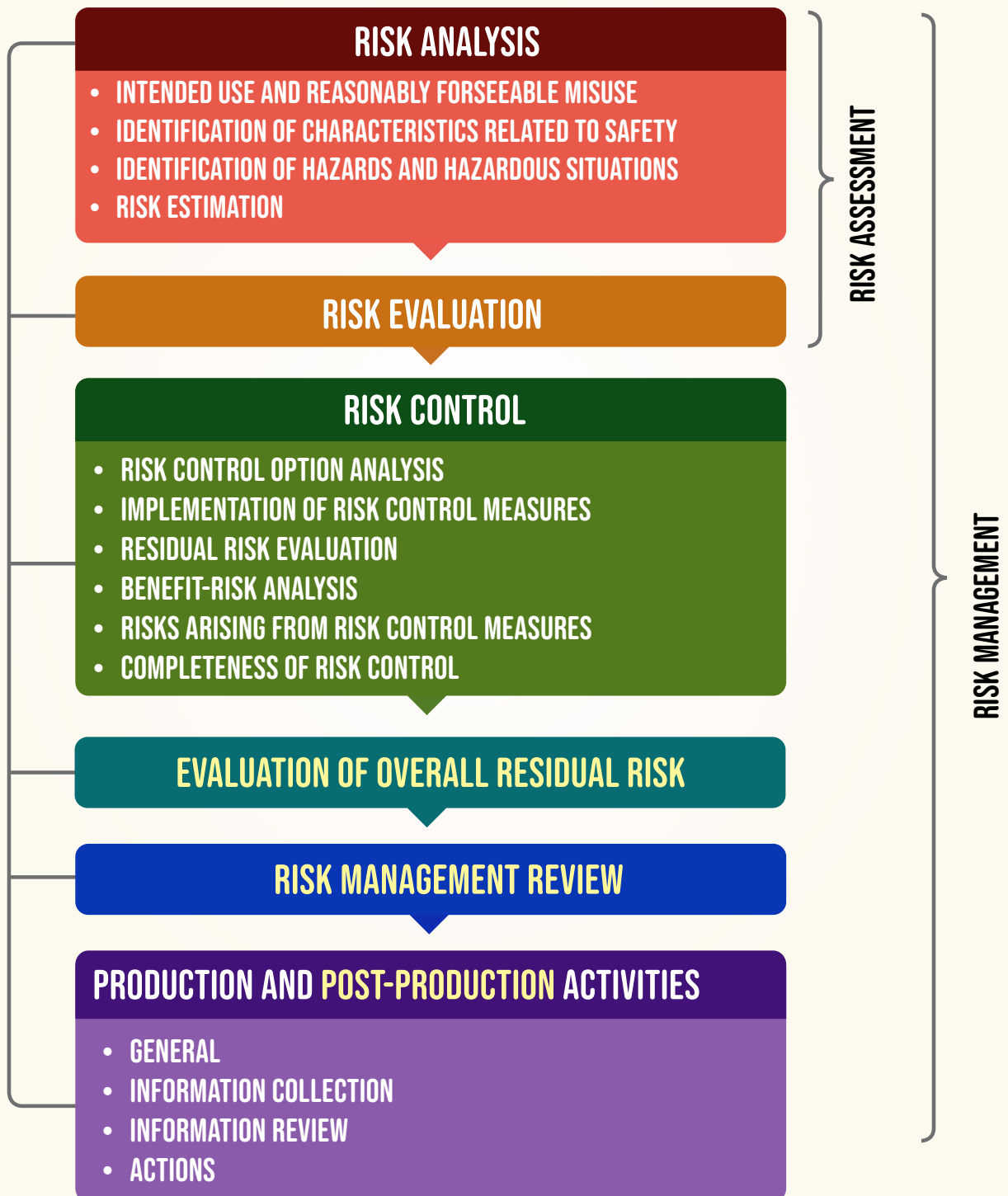
Vee VEE CARE (ASIA) LTD



MD 653109

PREPARING RISK MANAGEMENT REPORT

RISK MANAGEMENT PROCESS



PREPARING RISK MANAGEMENT REPORT

RISK MANAGEMENT

RISK MANAGEMENT PLAN

1. SCOPE
2. DEVICE DESCRIPTIONS
3. PERSONNEL AND RESPONSIBILITIES
4. RISK MANAGEMENT PROCESS
5. RISK ANALYSIS PROCESS
6. RISK EVALUATION PROCESS
7. RISK CONTROL MEASURE PROCESS
8. OVERALL RESIDUAL RISK
9. VERIFICATION OF RISK CONTROL MEASURES
10. RISK MANAGEMENT REVIEW
11. PRODUCTION AND POST-PRODUCTION ACTIVITIES

RISK MANAGEMENT REPORT

1. SCOPE
2. EVIDENCE AND VERIFICATION REPORTS
3. RISK ANALYSIS RESULTS
4. RISK EVALUATION
5. RISK CONTROL
6. EVALUATION OF OVERALL RISK
7. RISK MANAGEMENT REVIEW
8. PRODUCTION AND POST PRODUCTION ACTIVITIES
9. CONCLUSION
10. DESIGN RISK TRACEABILITY WORKSHEET
11. PROCESS RISK TRACEABILITY WORKSHEET
12. USER RISK TRACEABILITY WORKSHEET

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