

Ref No	Rev No.	Issue Date

Biological Evaluation Report

Product Name:

Company name :

Classification :

Duration of Use :

Raw Material / Material Characterization :

Sterilization :

Life Time :

STORAGE CONDITIONS :

Product Description:

Packaging:

Intended Purpose / indication :

Reference standards :

Criteria for Selection of tests required : (acc to Nature of body contact and contact duration)

Results of Biocompatibility Tests and Conclusion for every test :

Any comments or justification :

Clinical evaluation conclusion :

Residual Risk and Risk benefit analysis :

Final Conclusion

Attachment :

-qualification/ CV's for persons issue this report

- test reports from accredited lab and certification of accreditation for lab