CLINICAL EVALUATION PLAN

<Manufacturer Name>

<Street Address>

<City, State, Zip>

<Country>

DEVICE

<NAME>

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1 SUMMARY

Name of device(s)	
Device Indication(s)	
Target population	
Objective of this clinical evaluation	This Clinical Evaluation Plan has been produced in order to assess and analyse…
Device Claims	

2 SIGNATURE PAGE

Prepared by: _____

<Name>

<Title>

Date: _____

(…)

3 INTRODUCTION

3.1 Background

A manufacturer of a medical device is required to demonstrate that…

3.2 Objective of the Clinical Evaluation

This should be an expansion of the above but should include…

3.3 Clinical Evaluation regulations and Guidance

Clinical Evaluation on DEVICE will be prepared according to:

(…)