

# CLINICAL EVALUATION PLAN

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<Manufacturer Name>

<Street Address>

<City, State, Zip>

<Country>

## DEVICE

<NAME>

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## 1 SUMMARY

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

## 2 SIGNATURE PAGE

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Prepared by: \_\_\_\_\_

<Name>

<Title>

Date: \_\_\_\_\_

(...)

### **3 INTRODUCTION**

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#### **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:  
(...)