|  |
| --- |
| CLINICAL EVALUATION PLAN |
|  |
| <Manufacturer Name>  <Street Address>  <City, State, Zip>  <Country> |
| **DEVICE** |
| <NAME> |

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# 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 |  |

# SIGNATURE PAGE

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

<Name>

<Title>

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

(…)

# INTRODUCTION

## Background

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

## Objective of the Clinical Evaluation

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

## Clinical Evaluation regulations and Guidance

Clinical Evaluation on DEVICE will be prepared according to:

(…)