Case Study Report: Device Development Plan for an Insulin Infusion Pump to meet EU and US Regulatory Requirements

Making it the right way

TeaM Number

Date DD/MM/YYYY

2021

**Table of Contents**

[Executive Summary 2](#_Toc21274635)

[1. Introduction 3](#_Toc21274636)

[2. Identifying EU Regulatory Requirements for Your Insulin Infusion Pump. 4](#_Toc21274637)

[3. Identifying US Regulatory Requirements for Your Insulin Infusion Pump 5](#_Toc21274638)

[4. Comparing EU and US Regulatory Requirements for Your Insulin Infusion Pump 6](#_Toc21274639)

[5. Conclusion 7](#_Toc21274640)

[References 8](#_Toc21274641)

[Annex : Case Study Team Members 9](#_Toc21274642)

# Executive Summary

*Succinctly, yet accurately, describe the purpose of your Case Study, its major results, and a clear conclusion. This Executive Summary should not exceed half a page.*

# Introduction

*Briefly introduce the start-up company you have created to develop your Insulin Infusion Pump, its over-all business goal, and how you plan to develop your Insulin Infusion Pump for successfully meeting EU and US regulatory requirements.*

# Identifying EU Regulatory Requirements for Your Insulin Infusion Pump.

*Provide the results from Case Study – Exercise A.*

*Add some narrative, if you deem it useful for the reader.*

# Identifying US Regulatory Requirements for Your Insulin Infusion Pump

*Provide the results from Case Study – Exercise B.*

*Add some narrative, if you deem it useful for the reader.*

# Comparing EU and US Regulatory Requirements for Your Insulin Infusion Pump

*Provide the results from Case Study – Exercise C.*

*Add some narrative, if you deem it useful for the reader.*

# Conclusion

*Formulate the main results from your Case Study here.*

# References

*List the references cited elsewhere in this Case Study report here, e.g., EU Regulations, FDA regulations and guidance documents, IEC and ISO standards, and other relevant literature*.

# Annex : Case Study Team Members

*Provide the names and contact information (e.g., e-mail addresses) of the Team Members that developed this Case Study and Case Study Report. Identify the Team Leader.*