CHAPTER 3

HOW TO USE THIS GUIDEBOOK

As mentioned in the welcome chapter, this book is not meant to be read from cover to cover, it is a set of tools and references that you can use to ensure you have met the requirements of the MDR.

The book is broken into chapters that represent different tools you can use. Colour coding is used to aid navigation and each section of the book has a different coloured bar on the outside margin of the page to allow quick referencing. The colour coding of each tool is represented by the coloured line under each tool description below.

The starting point for most users of this guidebook will be Chapter 4 - Compliance Guide, which identifies what a manufacturer needs to do to comply with the MDR, from there, the tools can be navigated as required. The tool sets are as follows:

COMPLIANCE GUIDE:

The compliance guide is the starting point to aid compliance with the MDR. It provides an overview to the requirements of the MDR and helps a manufacturer build the documentation required to demonstrate compliance. This section also includes a list of 14 things that should be considered by a manufacturer.

DEVICE CLASSIFICATION

This lists the rules for classification and identifies what has changed from the Medical Device Directive. There is also a small section describing the type of devices that rule is intended for.

CLINICAL EVALUATION

This section provides some guidance on the requirements for clinical data and also has a notified body inspired checklist. This is a very large subject, so it provides a basic overview to help you get started.

CONFORMITY ASSESSMENT ROUTE ANNEXES:

This section provides a tabular view of the conformity assessment routes. It is a comparison tool that you can use to identify a preferred conformity route and the associated requirements.

QMS TABLES:

This chapter provides a set of useful tables that links the requirements of a Quality Management System to the requirements of the MDR, this can be used to ensure that your QMS procedures meet the necessary requirements.

TIMELINES:

The MDR has specific dates for implementation of different requirements. For example, UDI requirements will be applied for class III and Implantable device manufacturers on the 26th May 2021, which is a year after the general MDR applies.

MDR OVERVIEW ARTICLES:

This chapter provides an overview of the articles in the MDR. It describes each article and annex in simple terms, i.e. what it is about, a brief summary and also the conformity evidence required. A map is also provided to identify any links with other articles annexes.

MDR OVERVIEW ANNEXES:

This chapter provides an overview of the annexes in the MDR. It describes each article and annex in simple terms, i.e. what it is about, a brief summary and also the conformity evidence required. A map is also provided to identify any links with other articles annexes. Annex I includes a checklist for the safety and performance requirements and Annex III contains a PMS checklist.

INDEXES & LOOK UPS:

References have been collated and listed to allow review of further information. This list includes acronyms, delegating acts, other directives & regulation and a who's who in the MDR.

CHAPTER 4

COMPLIANCE GUIDE

INTRODUCTION

This chapter describes a high level process of where to start as a manufacturer looking to CE mark a device. Work through each flow diagram and table referring to the associated MDR section to guide you. A list is provided after the process flows and tables to ensure you consider other requirements that may apply to you.

PROCESS TABLE