PLEASE READ THIS FIRST

Thank you for downloading a free preview of our ISO 13485 & MDR Integrated Documentation Toolkit!

For an easier start, please read these few instructions:

1) The **documents in the Toolkit are sorted in a sequence** that should follow your implementation – folder #00 contains the Procedure for Document and Record Control (the best practice is to write this document first, even before you start your project) and related appendices; the next folder contains the Project Plan, and so on.
2) In the root folder of the Toolkit you'll find the file named **"List of documents"**, which describes some very important things: which documents from the toolkit are related to which ISO 13485 clause and/or MDR article, and which documents are strictly mandatory by ISO 13485 and/or EU MDR.
3) If you **receive an error opening certain files**, this is probably because the file name is too long – please copy the file to your Desktop and it should open normally there.
4) Soon, you will **start receiving tips and tricks** on how to fill in the templates via e-mail – if you don't start receiving these emails, please check your Spam folder.
5) Please read the **Terms of Use for Documentation** located in this folder.
6) Click here to see Pricing & Options.

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