ROADMAP TO CLASS I MDR COMPLIANCE

BASELINE STEP:

QMS Implementation

Integrate the MDR into your Quality Management System (QMS).

STEP 1

CONFIRM PRODUCT AS MEDICAL DEVICE

Check if your product meets the definition of a medical device per MDR, based on its intended purpose and principal mode of action. See MDR Article 2(1).

STEP 2

CONFIRM PRODUCT AS CLASS I

Confirm that your product is still classified as Class I device per classification rules set out in Annex VIII of the MDR.

STEP 3

MEET THE GSPRs

Check if your products meets the General Safety & Performance Requirements (GSPRs) as defined in Annex I of the MDR.
If not yet existing: Implement a risk management system. You will need it to comply with the GSPRs.

STEP 4

CONDUCT A CLINICAL EVALUATION

Even Class I devices need proper clinical evidence, so conduct a clinical evaluation.
Start with MEDDEV 2.7/1 Rev. 4, but also consider the following aspects from MDR Article 61:

(a) All available alternative treatment options are considered.

(b) Clinical data obtained over the device life cycle from PMCF and PMS is incorporated.

(c) The benefit-risk ratio is based upon sufficient clinical data and is continuously reassessed from clinical data collected through PMS.

STEP 5

PREPARE YOUR TECHNICAL DOCUMENTATION

Ensure that all relevant aspects listed in Annex II and III of the MDR are addressed in your Technical Documentation, and, keep it up to date!

STEP 6

REQUEST NOTIFIED BODY INVOLVEMENT

In the case of devices placed on the market in sterile condition, having a measuring function or being reusable surgical instruments, you need involvement of a Notified Body (NB). Involvement of the NB is then limited to the special conditions of your device, e.g. sterility, measurement function, reprocessing.

STEP 7

PREPARE IFU AND LABELLING

Your device must be accompanied by information for safe use, so create your instructions for use (IFU) and labelling. No IFU is required for Class I devices if they can be used safely without such instructions. Consider national languages, use symbols and label your device as 'medical device'. Detailed content information can be found in MDR Annex I, Chapter III (23).

STEP 8

COMPLY WITH GENERAL OBLIGATIONS

Check out MDR Article 10 and ensure that your company complies with the general obligations described therein. Pay special attention towards your QMS compliance.

STEP 9

DRAW-UP THE EU DECLARATION OF CONFORMITY (DOC)

With the EU DoC you declare that your device fulfills the requirements of the MDR. The DoC contains as a minimum all information shown in MDR Annex IV. For class Ir, Im and Is devices you will have an EC certificate issued by your NB according to the Annex IX, Chapter I and III, or to Annex XI, Part A.

STEP 10

AFFIX THE CE MARKING

Affix the CE mark on the device. Place a CE mark also in your IFU and on any sales packaging. For Is, Im and Ir devices add the NB identification number to the CE mark.

STEP 11

EUDAMED REGISTRATION

Register your company and Class I device in Eudamed. Until Eudamed is fully functional you must inform your Competent Authority (CA) and provide a device description. Contact your CA for the right procedures and forms.

STEP 12

POST MARKET SURVEILLENCE (PMS)

Congratulations, you are on the EU market!
Now follow your device specific PMS Plan, your actions should include:

(a) Continuous PMS report and technical documentation updates, including clinical evaluation, risk management & benefit-risk determination per MDR Article 83ff.

(b) Vigilance and trend reporting per MDR Article 87ff.

(c) Management of non-conforming products by correction, withdrawal or recall.

Roadmap is based on MDCG Guidance '2019-15 GUIDANCE NOTES FOR MANUFACTURERS OF CLASS I MEDICAL DEVICES December 2019'

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