# 10 STEPS FOR THE EUROPEAN CE MARKING PROCESS ACCORDING TO MDR

Please see MDR (EU) 2017/745 and Guidance notes, especially MDCG 2019-15.

## STEP 1

### IS YOUR DEVICE A MEDICAL DEVICE?

Formulate the intended purpose (clinical claim) of the device. What are the clinical benefits for the patient, patient group or public health? What are indications, contra-indications, patient target group or groups, and the intended users. Please note that you must provide evidence that the device is safe and effective for all patient groups (neo-natals, infants, aged, people with other healt problems) and all environments (home, -20 °C, +45 °C and RH 95) that are not excluded directly or indirectly.

Determine if your device is a medical device, based on definition of Article 2. Please see European Commission website for more information.

## STEP 2

### DETERMINE CLASSIFICATION AND AQUIRE SRN

Determine classification of the device using rules of Annex VIII of the MDR: Class I, Class I (sterile, measuring, reusable surgical instrument), Class IIa, Class IIb or Class III.

It is recommended to contact national authorities (Competent Authority, CA) at this step to get information of possible requirements for national registration. Acquire a Single Registration Number (SRN) for your company from the CA or from the EUDAMED, once it is operational (please see Article 31 and Annex VI)

## STEP 3

### IMPLEMENT A QMS

Implement a Quality Management System (QMS) in accordance with Article 10 of the MDR. Most companies will apply the EN ISO 13485 standard to meet the key requirements of the MDR.

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## STEP 4

### PREPARE DOCUMENTATION

PrepareTechnical Documentation that provides detailed information and evidence on how your medical device complies with the MDR Annex I - General Safety and Performance Requirements (GSPR).The structure of documentation is specified in the Annex II - Technical Documentation

For Class III and active implantable devices your must prepare a Design Dossier. Please note that all medical devices will require Clinical Evaluation as part of the Technical Documentation. Please note that Class III and implantable medical devices will typically require Clinical Investigation to be undertaken. Additional guidance is available through MEDDEV documents 2.7/1 and 2.7/4. Note especially the minimum requirements for Clinical Evaluation Report (CER) and the process to compile the CER that is defined in MEDDEV 2.7/1. While technically the MEDDEVs will not apply to MDR, they still can be used as a recommended guideline.

Most of the manufacturer's have applied compliance to harmonized standards as evidence for complying with Essential Requirements of the directive(s). At the moment there are no harmonized standards for MDR, but majority of the notified bodies are expected to accept the same standards as the state of the art for MDR. Please note that if a compliance test report is not issued by a competent conformity assessment body that is independent from the manufacturer, the NB cannot accept the report as evidence.

## STEP 5

### APPOINT AN EU AUTHORIZED REP

If your company is located outside of the EU, appoint an Authorized Representative (EC REP) located in the EU with a written agreement.

The Authorized Representative should be qualified to handle regulatory issues. Place EC REP name and address on Technical File, Declaration of Conformity, Instructions for Use and packaging. Additional guidance is available through Article 11 and MEDDEV document 2.5/10.

## STEP 6

### APPOINT A NOTIFIED BODY

For all devices except Class I (non-sterile, non-measuring, non-reusable surgical instrument), you must appoint a Notified Body to audit and review your QMS and Technical File or Design Dossier, depending on the selected conformity route. The appointed Notified Body must have your device category in their notified scope. Please see Nando database.

## STEP 7

### GET EUROPEAN EC CERTIFICATE

For all devices except Class I (nonsterile, non-measuring, non-reusable, surgical instrument), you need to be issued an European EC Certificate for your device, following a successful completion of your Notified Body audit and technical documentation assessment. You may also want to have a voluntary ISO 13485 certificate for your facility that is required by many customers and regulators. The certificates are typically valid for 5 years. There will be an annual surveillance audit and the certification must typically be renewed every 3 years.

## STEP 8

### REGISTER IN THE EUDAMED

All medical devices must be assigned Unique Device Identifier as defined in Parts B and C of Annex VI and registered in the Eudamed system. Please see European Commission website for further information.

## STEP 9

### PREPARE A DECLARATION OF CONFORMITY

Prepare a Declaration of Conformity (DoC), a legally binding document signed by the manufacturer's authorized person. The DoC contains a set of mandatory information and states that the device is in compliance with the applicable Directive(s), Regulations and other legislation. Please see Official Journal of the EU 2016/C272/01 and Annex IV of MDR for detailed requirements of DoC.

## STEP 10

### AFFIX THE CE MARK

When all the previous steps have been completed, you may now affix the CE Marking. For Class Im, Is, Irsi, or higher the CE Mark must include the notified body number.

Note: The new Medical Devices Regulation 2017/745 has entered into force on 26th May 2017 and will substitute the MDD 93/42/EEC from 26 May 2020. EC certificates based on 93/42/EEC, issued before 25 May 2020, will have maximum validity until 26 May 2024, if the last validity date on the certificate does not come first.


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