Classification

The next step is to classify the software product according the MDR. Dependent on their intended use and possible risks to the patient, the MDR defines the following classification:

Class	Characteristics	Events
Class I	Lowest risk	Draw up Technical File (TF), see section Technical File (TF) Registration with Competent Authority. Self-declare CE and put on the EU market Execute Post Market Surveillance (PMS), see section Post Market Surveillance (Unannounced) audits by Competent Authority
Class Is	Sterile device	Draw up Technical File), see section Technical File (TF) Submit Technical File to Notified Body. Notified Body certificates CE. Put on the EU market Execute Post Market Surveillance, see section Post Market Surveillance Notified Body audits yearly & unannounced.
Class Im	Device with measuring function	
Class IIa	Medium risk	
Class IIb	Medium to high risk	
Class III	Highest risk	

Classification to one of above classes is achieved by following the MDR classification rules.

For software, the following rule(s) apply:

> Implementing rule 3.3

Software, which drives a device or influences the use of a device, shall fall within the same class as the device. If the software is independent of any other device, it shall be classified in its own right.

> Classification rule 11:

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

- death or an irreversible deterioration of a person's state of health, in which case it is in class III; or
- a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.

Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.

All other software is classified as class I.

In case the vendor is unsure how its device should be classified, it should first consult a Notified Body.