

## MEDDEV 2.7/1 – new guidelines on clinical evaluations



On 29 June 2016 the [European Commission](#) released a new version of **MEDDEV 2.7/1**, entitled “Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under Directive 93/42/EEC and 90/382/EEC”. The recently issued file replaces the 2009 version. It outlines **clear guidelines** for both **manufacturers** and **Notified Bodies** on how to conduct [clinical evaluation](#) of **medical devices**.

### What is MEDDEV 2.7/1?

Conduct of [clinical evaluation](#) is currently **mandatory** in [the EU](#) for all classes of medical devices prior to affixing the [CE mark](#). Any **medical devices’ manufacturer** is **obliged** to complete the **clinical evaluation**, which is documented in the **clinical evaluation report (CER)**. CER is an integral part of the [Technical File](#). The main aim of [MEDDEV 2.7/1](#) is to set out guidelines concerning the purpose, methodology and necessary documentation of a [clinical evaluation](#).

### What has changed?

The [2016 version](#) includes more detailed requirements for **clinical data**, acceptable methods, **frequency of updates** and the evaluation of CER.

Some of the **key changes** include, but are not limited to:

- preliminary stage of [clinical evaluation](#) added (referred to as ‘Stage 0’)
- clear deadlines for the frequency of [clinical evaluation](#) update (annually or every 2-5 years)
- revised definition of devices’ equivalence
- new requirements for the evaluators of clinical data

It is assumed that the new version of [MEDDEV](#) takes a step in the direction of the [new Medical Devices Regulation](#). It will assist manufacturers in preparing for complying with the new requirements brought by the [upcoming legislation](#).

**Where can I access MEDDEV 2.7/1 text?**

The **entire text** of the MEDDEV 2.7/1 is now **available on Obelis website** in the [Legislation section](#). If you wish to know more about [clinical evaluation](#) and the [CE marking process](#) for medical devices, feel free to [contact us](#).