Avoid Losing a CE Mark Cheat Sheet

by [deleted] via cheatography.com/2754/cs/9250/

Introduction

A Clinical Evaluation Report (CER) is part of the process through which a medical device is certified or recertified to carry the CE mark; it applies to all device classifications. A company may have complied with the quality aspects of its ISO 13485 certification, but it also needs to comply with the technical documentation required by the Medical Device Directive (MDD), which includes the CER.

Every five years, a company's Notified Body (NB) formally reviews the CE mark status for a medical device distributed in Europe. For many medical devices, that means CERs must be submitted now. Recently, NBs have intensified their scrutiny of CERs. This has left many medical device companies scrambling to remediate their CERs before the five-year window expires and jeopardizes the CE mark status of their product.

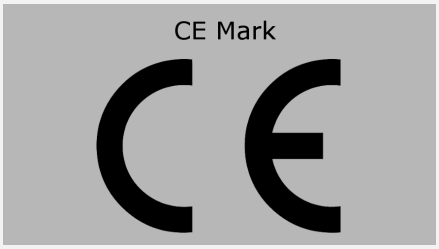
CERs have always been required as part of CE mark recertification. NB-MED/2.5.1/Rec5 (2010), titled "Technical Documentation," notes (in essence), "If you are going to create a technical file or a design dossier, you must have a CER; here is the guidance for it." (NB-MED/2.5.1/Rec5 can be found at: http://bit.ly/2016cer1. A recommendation for the evaluation of clinical data, titled, "Evaluation of Clinical Data" (NB-MED/2.7/Rec3 [2010]), can also be found at the same URL.)

Overall, companies have been submitting satisfactory CERs for high-risk (Class III) devices. However, CERs submitted for lower-risk devices have, in general, not been so rigorous. Those CERs, although not rejected by the NBs, did not completely or correctly follow the guidance for CER submissions as described in MEDDEV 2.7.1, Rev. 3 (Clinical evaluation: Guide for manufacturers and notified bodies [2009]; http://bit.ly/2016cer2).

http://www.odtmag.com/issues/2016-08-01/view_columns/four-questions-to-help-you-avoid-losing-a-ce-mark

Conclusion

C E



Question to Help Avoid Losing CE Mark

The European Commission (EC) guidance for CERs is similar in concept to the type of guidance issued by the U.S. Food and Drug Administration. The main reason NBs reject CERs is because companies submitting the CERs did not follow the guidance correctly. For example, many companies have been conducting data reviews of existing data only, and not the entire analysis as required by the guidance?

If NB regulators cannot follow how a submission flows and determine whether it is meeting the guidance, they will inform the company and delay the CE marking.

Although some companies may understand the guidance, they may not have the resources to comply with it; CERs are very resource-intensive. If that is the case, companies should seek external resources (e.g., agencies or consultants) experienced in submitting CERs. External resources can be used, in part or in whole, to research and write CERs.

When selecting an external resource, ensure that resource can do more than simply identify areas of CER noncompliance. A good consultant will not only help a company understand where the process gaps are, but will also help it develop and implement a clear plan to resolve those gaps and improve its overall process.

1. Why did the NBs accept subpar CER submissions in the past?

Simply put, and for reasons not completely known, NBs were not enforcing the content and format of lower risk product CERs. The authorities overseeing the NBs are now requiring that their NBs ensure all medical devices in the European market wanting to receive or retain a CE mark have a compliant CER.

2. Why is the push for stricter compliance occurring now?

ISO 14971 (Medical devices—Application of risk management to medical devices) underwent a major revision in 2012 and became a European Norm (EN). An EN is a law in Europe, which means it must be followed. An EN ISO is more enforceable than an ISO. The risk management changes in EN ISO 14971:2012, based on the Medical Device Directive (MDD), are also reflective on the clinical risk evaluations required in the CER. EN ISO 14971:2012 has given CERs more visibility. The EN ISO 14971:2012 standard may be purchased at www.iso.org, or from any organization licensed to sell the standard.. Companies might have two different challenges:

■A risk management process that, according to EN ISO 14971:-2012, is not meeting the standard

■A CER that is not meeting the directive, which is evaluated by the MEDDEV document

3. Why the urgency around CER submissions?

Many companies that received their CE mark certification before 2012 have begun submitting revised CERs as part of the five-year review cycle for their products. They have been surprised to find their NBs are rejecting their submissions due to noncompliance with MEDDEV guidance, even though past submissions had been accepted. Without a compliant CER, the CE mark for a product can be delayed and even withdrawn, resulting in a company no longer being able to sell that product in Europe (or any member states of the European Union).. **4. What can my company do now?**

A. Obtain and review the relevant CER guidance, and make sure it is completely understood. If there are any questions, seek assistance from an expert.

B. Conduct a gap analysis to determine whether or not your CER meets the requirements of the MEDDEV.

C. Identify any noncompliant issues.

D. Fix those issues to bring the CER into compliance with the MEDDEV. If an existing CER is highly noncompliant, writing a new CER may be preferable to amending the existing CER.

E. Create a standard operating procedure on how to write CERs, or update the existing one, and include a template in the appendices.