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BSI Medical Device Newsletter: October 2015

Welcome to the October Medical Device Newsletter 2015

Medical Device and IVD Directives revision update

Following the June 19 partial agreement in the European Council, the Council has continued writing their take on the recitals that justify the intent of the legislation and some of the key changes. In addition, they have made some technical corrections to their agreed texts. For now, the last Council workgroup for this stage is scheduled for the first week of October.

The Council Workgroup as well as the Parliaments rapporteurs and shadow rapporteurs, after their summer breaks, have started to prepare for their positions in the trilogue negotiations. Some of the elements in the debate are relatively new, such as the grandfathering options, or selective assessment schemes, for products already on the EU market. These will start mid-October, with six meetings scheduled at this stage: three in October, two in November and one in December. Significant preparation will go into each of these highly focussed sessions, the first of which will concentrate on chapters I and Annexes I-V of both MDR and IVDR, including one of the key topics of disagreements: the addition of predictive and genetic testing.

Latest white paper from BSI

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The new white paper by Mark Swanson and Bill Enos, introduces the proposed updates to ISO 13485, many of the changes are current best practice and can be immediately addressed.

To download this and other white papers please visit our website.

With this push Luxembourg, the current chair of the European Union, is trying to achieve great steps towards finalization. If they are successful in reaching compromises on further key topics such as:

- clinical studies versus literature
- scrutiny process
- notified bodies and their supervisory structures
- reprocessing of single use device

When the final Council view is completed and the first reading vote finished, if negotiations are advanced enough to finish and agree on the two documents shortly after a second reading in Parliament and Council. Considering the timelines, the last steps will be coordinated by the Dutch presidency.

Assuming a positive scenario, legislation may be finished towards the middle of 2016.

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BSI and CSA will be exhibiting at the world wide Medical Trade Fair from November 16 to 19 2015, Hall 10 booth 10E03 in Düsseldorf, to arrange a meeting please visit our joint site.

open for registration:

ASEAN Medical Device Directive (AMDD) A brief Overview
11th November

Medical Device Software - do you understand how software is regulated?
20th November

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