ascom

To whom it may concern

Statement regarding EN 60601-1-8 for Europe, "General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems"

This statement is intended to clarify the Ascom understanding of the application of the harmonized standard EN 60601-1-8 (see details about the standard and its amendment below). New information of date of withdrawal (DOW) and replacement of the current standard has been presented by the standardization body (CENELEC). The new date is 2018-12-31.

To become a harmonized standard for Europe, publication will be made in the EU Official Journal. It is today not known when or what DOW will be published in the OJ. Until this publication is made, the current harmonized standard is applicable.

As of today;
The harmonized standard relevant to an Ascom distributed alarm system is the EN 60601-1-8:2007. This standard-, in combination with other applicable harmonized standards-, and by its publication in the Official Journal (OJ), gives Ascom a presumption of conformity with the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices. The first publication in OJ of the EN 60601-1-8:2007 was 2008-11-27, replacing the amended EN 60601-1-8:2004 with an expiry date set to 2012-06-01. The expiry date of EN 60601-1-8:2004 (DOW of 2012-06-01) was added to the EN 60601-1-8:2007 in a corrigendum, the EN 60601-1-8:2007/AC:2010.

The published EN 60601-1-8/A1:2013, that amends- and modifies the EN 60601-1-8:2007 was approved by CENELEC in 2013-01-02. In 2014-05-09 a corrigendum was published, the EN 60601-1-8:2007/A1:2013/AC:2014. This corrigendum specifies that the EN 60601-1-8:2007 won't be valid without the amendment, EN 60601-1-8/A1:2013 after 2018-12-31 (DOW).

The amendment EN 60601-1-8/A1:2013 and its corrigendum EN 60601-1-8:2007/A1:2013/AC:2014 has not yet been published in the OJ. As a consequence; this amendment do not give Ascom a presumption of conformity with the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices.

However;
It can be expected in a future publication of the OJ, that the corrected amendment, EN 60601-1-8/A1:2013 will be included as a harmonized standard. It can also be expected that the date specified, when the EN 60601-1-8:2007 won't give presumption of conformity with the Directive 93/42/EEC without the amendment EN 60601-1-8/A1:2013, will be set to 2018-12-31. If, published, the requirements stated in EN 60601-1-8/A1:2013 will be required for an Ascom distributed alarm system.

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