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[Page numbers are from the Guidance document .PDF file]

GENERAL:

The standards referenced follow those listed in the EU Harmonised Standards MDD
<<http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/relist/meddevic.html>>, but they are not necessarily current. Several have been updated by their author organizations, such as:

IEC 60601-1-2:2001 (pages 7, 9, cf.) versus IEC 60601-1-2 Ed. 2.1 b:2005

ISO 14971:2000 (page 11) versus ISO 14971:2007

It would be helpful in the document to provide a note wherever a referenced standard has a more recent approved version; in some cases it may be appropriate to consider recommending the newer version.

PAGE 7, section on "Performance of wireless function":

The statement that labeling should specifically include "...the testing performed and your results..." could result in user documentation with data too detailed and/or too technical; suggestion is to reword this as "...summary of testing performed and your results...".

PAGE 8:

Typo: "...personnel digital assistants..." should be "...personal digital assistants..."

PAGE 21, section 10, last paragraph ref incoming product inspection:

Since this may include off-the-shelf components that may not require actual testing, the suggestion is to change "testing and inspection" to "testing and/or inspection".

PAGE 25, description of 802.11g:

It would be useful to provide more details on 802.11g. Although it uses the same general frequency range as 802.11b, it has significant other enhancements such as support of more advanced modulation techniques such as OFDM and a theoretical maximum speed of 54 Mbp. Details such as these are noted in the Guidance document description of 802.11a so should also be in the description of 802.11g.

PAGE 28, section in Appendix B referring to IEEE standards:

The list of IEEE standards would be more useful if it was clarified and additional details were provided.

"IEEE 1073.x" is now more commonly referred to as "ISO/IEEE 11073".

"IEEE 802.x" usually is used as reference to general Ethernet standards; it would be more appropriate to replace this with references to the wireless-specific standards, i.e. "IEEE 802.11x" for WLAN and "IEEE 802.15x" for WPAN (wireless personal area network such as Bluetooth).

In addition to those general references, it would be helpful to provide a set of the important wireless standards that are, or are likely to be, associated with wireless medical devices, i.e.

ISO/IEC 8802.11: 1999 [IEEE Std 802.11-1999 (R2003)] Part II:
Wireless LAN Medium Access Control (MAC) and Physical Layer (PHY)
Specifications

802.11b - 1999 Higher Speed PHY Extension in the 2.4 GHz Band

802.11a - 1999 Higher Speed PHY Extension in the 5GHz Band

802.11g - 2003 Further Higher Data Rate Extension in the 2.4 GHz
Band

802.11i - 2004 MAC Security Enhancements

802.11e - 2005 MAC Enhancements (QoS)

and

802.15.1 - 2005 Wireless Personal Area Networks (WPANs(tm))

Clarification of the meaning of the term "Wi-Fi", and what modalities can actually be associated with it, would be useful.

A reference to the works-in-progress 802.11n high-throughput multi-band 2.4/5 GHz standard may be useful due to the current publicity generated by it and the resulting rapid deployment expected once it is approved.