Global Medical Technology Alliance

Innovating for a Healthier World

GMTA

New Work Item Proposal

List of International Standards recognized by IMDRF Management Committee Members Phase II

March 25, 2015

Global Medical Technology Alliance
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Background:

- Phase One Final Report issued March 2014
- Standards recognized by majority of MC members listed in Phase I Report
- MC members to update lists on ad hoc basis
- Outcome of September 14 IMDRF meeting: MC members to publish individual list of recognized standards

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Phase II Proposal

Goal: To promote regulatory harmonization through greater use and acceptance of international standards:

Identify a core list of horizontal international standards

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Core list of standards for consideration

Quality Systems: ISO 13485

Risk management: ISO 14971

Electrical Equipment: IEC 60601

Electrical Equipment for Laboratories: IEC 61010

Software: IEC 62304

Biological evaluation of medical devices (all parts): ISO 10993

Clinical investigation of medical devices: ISO 14155

Core list of standards for consideration

Symbols to be used in medical device labels: ISO 15223

Sterilization: ISO 11135, ISO 11137, ISO 17665, ISO 20857

Usability: IEC 62366

Aseptic Processing: ISO 13408

Use of animal tissues/derivatives: ISO 22442

Packaging (all parts): ISO 11607

Take steps to ensure Management Committee members recognize core standards

- Identify obstacles for not fully recognizing each standard

- Set goals for full recognition of core standards