IMDRF

소프트웨어의료기기(SaMD)

실무그룹 업무 현황

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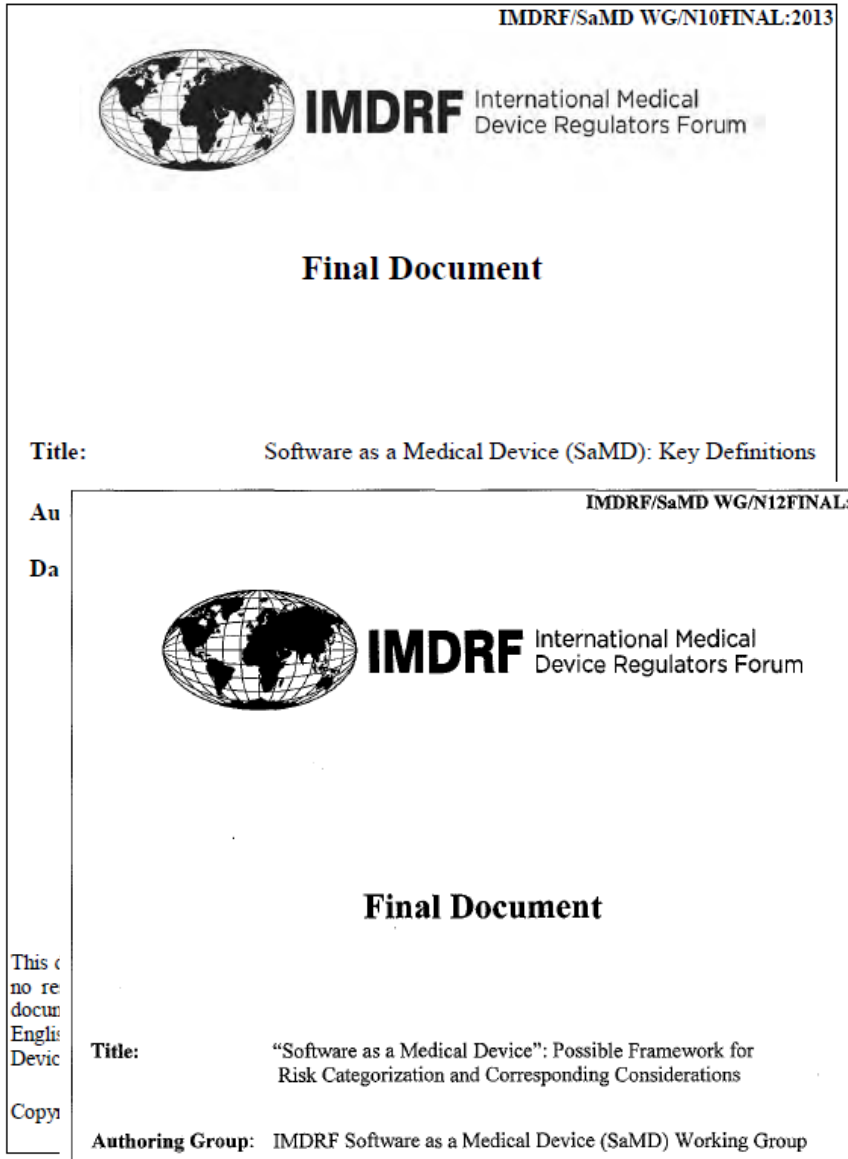
목차

I. 실무그룹 개요

Purpose and Rationale

Software for medical purposes continues to be increasingly important and influential in advancing public health. The Software as a Medical Device (SaMD) Working Group (WG) published the last of 4 technical documents it authored in 2017. Since 2017 both regulations related to medical purpose software as well as progress and pace of technological advancement have been numerous. The goal of this extension is to refine the previously published documents to ensure ongoing consistency, predictability, transparency, and quality of premarket regulatory programs and criteria for assessing premarket technical documentation for SaMD but also to expand attention to post-market activities recognizing the speed with which digital health technology moves and the value of taking a total product life cycle approach aligned with the principles of IMDRF. As appropriate, and based on the results of a future gap analysis/survey, the WG may identify the need for additional documents.

I. 실무그룹 개요



IMDRF/SaMD WG/N10FINAL:2013

IMDRF International Medical Device Regulators Forum

Final Document

Title: Software as a Medical Device (SaMD): Key Definitions

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IMDRF/SaMD WG/N12FINAL:2014

IMDRF International Medical Device Regulators Forum

Final Document

Title: "Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations

Authoring Group: IMDRF Software as a Medical Device (SaMD) Working Group

Date: 18 September 2014

IMDRF/SaMD WG/N23 FINAL: 2015

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

International Medical Device Regulators Forum

Title: Software as a Medical Device (SaMD): Application of Quality Management System

Authoring Group: IMDRF SaMD Working Group

Date: 2 October 2015

Toshiyoshi Tominaga, IMDRF

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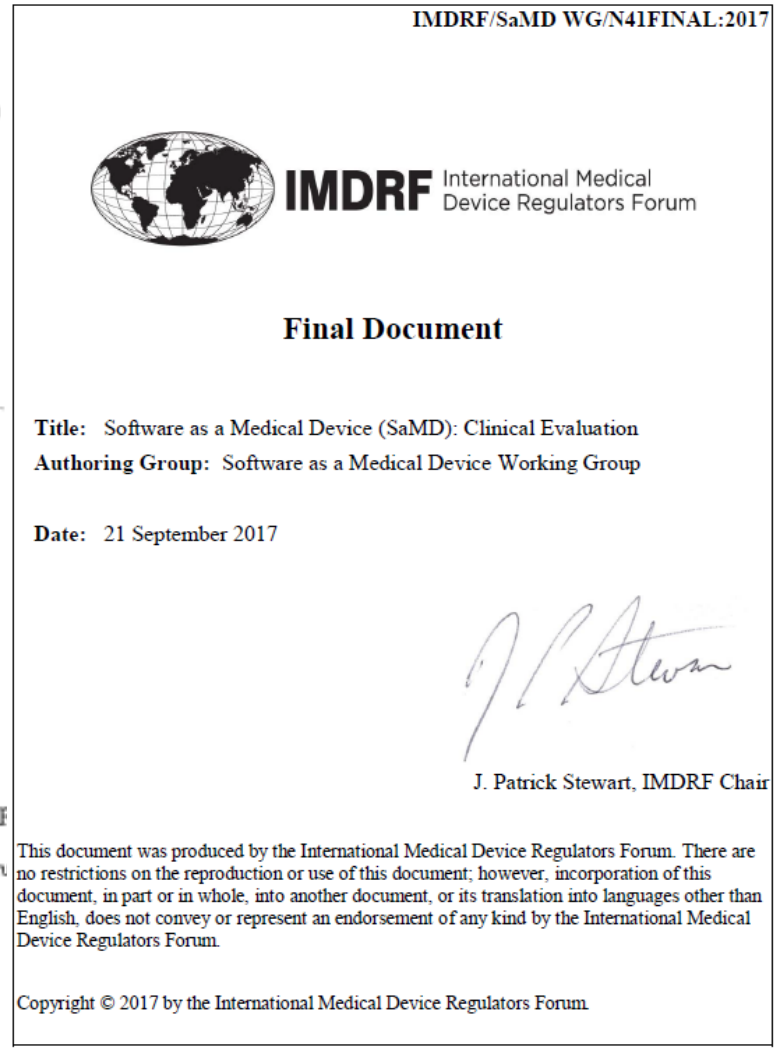

IMDRF/SaMD WG/N41FINAL:2017

IMDRF International Medical Device Regulators Forum

Final Document

Title: Software as a Medical Device (SaMD): Clinical Evaluation

Authoring Group: Software as a Medical Device Working Group

Date: 21 September 2017

J. Patrick Stewart, IMDRF Chair

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II. 실무그룹 주요 논의사항

1. How are you utilizing the IMDRF Risk Categorization Framework?
2. What challenges do you have utilizing the IMDRF Risk Categorization Framework?
3. What benefits have you experienced utilizing the IMDRF Risk Categorization Framework?
4. What changes do you propose for the IMDRF Risk Categorization Framework?
5. Are there additional IMDRF SaMD documents which may benefit from an update? If so, describe the challenges and any proposed changes.

III. 실무그룹 주요 추진사항

General Work Plan and Timelines

The working group's activities would be conducted via teleconferences. The proposed refinement of previously published IMDRF SaMD documents is expected to take 24 months with draft documents submitted to the Management Committee within 18 months and the additional 6 months would be utilized to receive comments and provide resolution for final submission.

The project includes the below steps:

- Identify working group members
- Perform gap analysis/survey regarding each previously issued IMDRF SaMD document compared to advances in regulatory science and current practices
- Review alignment to documents/work performed in the Artificial Intelligence Medical Devices WG, the Medical Device Cybersecurity Guide and other WG as appropriate.
- Propose changes needed to previously issued IMDRF SaMD documents and/or the need to develop additional documents.
- Revise previously issued IMDRF SaMD documents and if necessary, prepare outline for new document.
- Publish proposed draft(s) for public comment
- Publish final documents

Thank you

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