



IMDRF 사이버보안(CYBER)

실무그룹 업무 현황

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I. 실무그룹 개요

Purpose


To facilitate international regulatory convergence on medical device cybersecurity with open discussion and sharing best practices that are understandable and feasible for all stakeholders supporting innovation and timely access to safety and effective medical device globally.

Rationale

Convergence of global healthcare cybersecurity efforts is necessary to ensure that patient safety is maintained and innovation is encouraged. But current disparate regulations between national and international agencies do not provide the consistency needed to ensure that medical device cybersecurity contributes to this goal.

I. 실무그룹 개요

IMDRF/CYBER WG/N60FINAL:2020




IMDRF International Medical
Device Regulators Forum

FINAL DOCUMENT

Title: Principles and Practices for Medical Device Cybersecurity

Authoring Group: Medical Device Cybersecurity Working Group

Date: 18 March 2020



Dr Choong May Ling, Mimi, IMDRF Chair

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II. 실무그룹 주요 논의사항

IMDRF/CYBER WG/N70



IMDRF International Medical
Device Regulators Forum

DRAFT DOCUMENT

Title: Principles and Practices for the Cybersecurity of Legacy Medical Devices

Authoring Group: Medical Device Cybersecurity Working Group

Date: April/May 2022

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IMDRF/CYBER WG/NXXDRAFT:2022



IMDRF International Medical
Device Regulators Forum

DRAFT DOCUMENT

Title: Principles and Practices for Software Bill of Materials for Medical Device Cybersecurity

Authoring Group: Medical Device Cybersecurity Working Group

Date: July 2022

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II. 실무그룹 주요 논의사항

IMDRF CYBER WG(사이버보안 실무그룹) 주요 업무 및 의장

- **(N70*)** ‘레거시 의료기기 사이버보안 원칙 및 모범사례’ 가이드라인 개발

* IMDRF/CYBER WG/N70PD:2022 "Principles and Practices for the Cybersecurity of Legacy Medical Devices"

* 현재 초안에 대한 2달간의 공개의견수렴 기간(~'22.7.3.) 후, 실무그룹 논의 개시함

- **(N73*)** ‘의료기기 사이버보안 소프트웨어 구성명세서(SBOM**)에 대한 원칙 및 모범사례’ 가이드라인 개발

* IMDRF/CYBER WG/N73PD:2022 "Principles and Practices for Software Bill of Materials for Medical Device Cybersecurity"

* 현재 초안에 대한 2달간의 공개의견수렴 기간 중(~'22.8.30.)

** (SBOM, Software Bill of Materials) 제조부문에서 유래된 개념으로, 소프트웨어 전체에 대한 모든 구성요소를 명기한 목록으로서 특정 장치 제작에 사용된 구성요소와 재료를 낱낱이 파악하는 데 중요한 역할을 함

- **(공동의장*)** Suzanne Schwartz (미국) & Marc Lamoureux (캐나다)

III. 실무그룹 주요 추진사항

- N70, N73 가이드라인 최종안 마련을 위한 실무그룹 논의(~'22.11)
 - * 2건의 가이드라인 최종안 마련을 위한 대면회의 대체 실무그룹 원격회의 ('22.11.8~10 또는 '22.11.15~17) 예정
- 2건의 가이드라인 최종안 제출(1월 중 예상)하여, IMDRF 운영위원회 검토(7주)를 거쳐, 최종 승인 목표('23.3, 22차 IMDRF 운영위원회 회의)



Thank you



식품의약품안전처