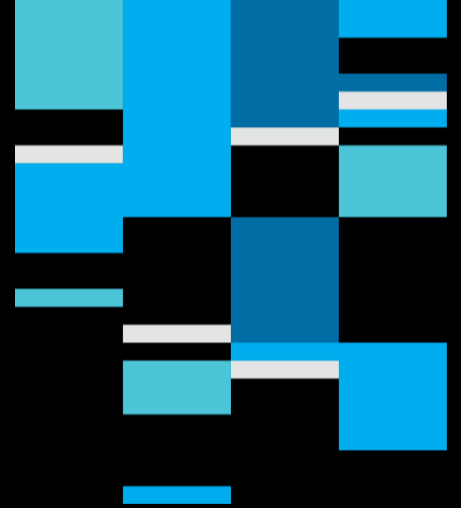


# IEEE MEDICAL DEVICE CYBERSECURITY STANDARD & CERTIFICATION PROGRAM

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# INDUSTRY LED DEVELOPMENT

- **Standards Approved** – March 2021, IEEE Board approval
- **Test Plan approved** – December 2022, IEEE Certification Advisory Committee approval
- **Pilot Testing** – Started in Q1 2023, **first certifications expected in Q1 2024**
  
- **Strong industry support** – 17+ companies including major security vendors
  - Standards and Cert. Program developed under the leadership of Dr. David Klonoff (DTS) and Dave Kleidermacher (Google)
- **Strong regulatory support** – standard already included in FDA's catalog of standards



# CYBERSECURITY ECOSYSTEM FOR INDUSTRY



- FDA is setting the bar – cybersecurity capabilities now required by LAW

## Current Scope of the IEEE Certification Program: Connected diabetes devices

- BGM, CGM, Insulin Pump, Insulin Pen, Closed Loop System/AID system,...

## Future Scope: All medical devices

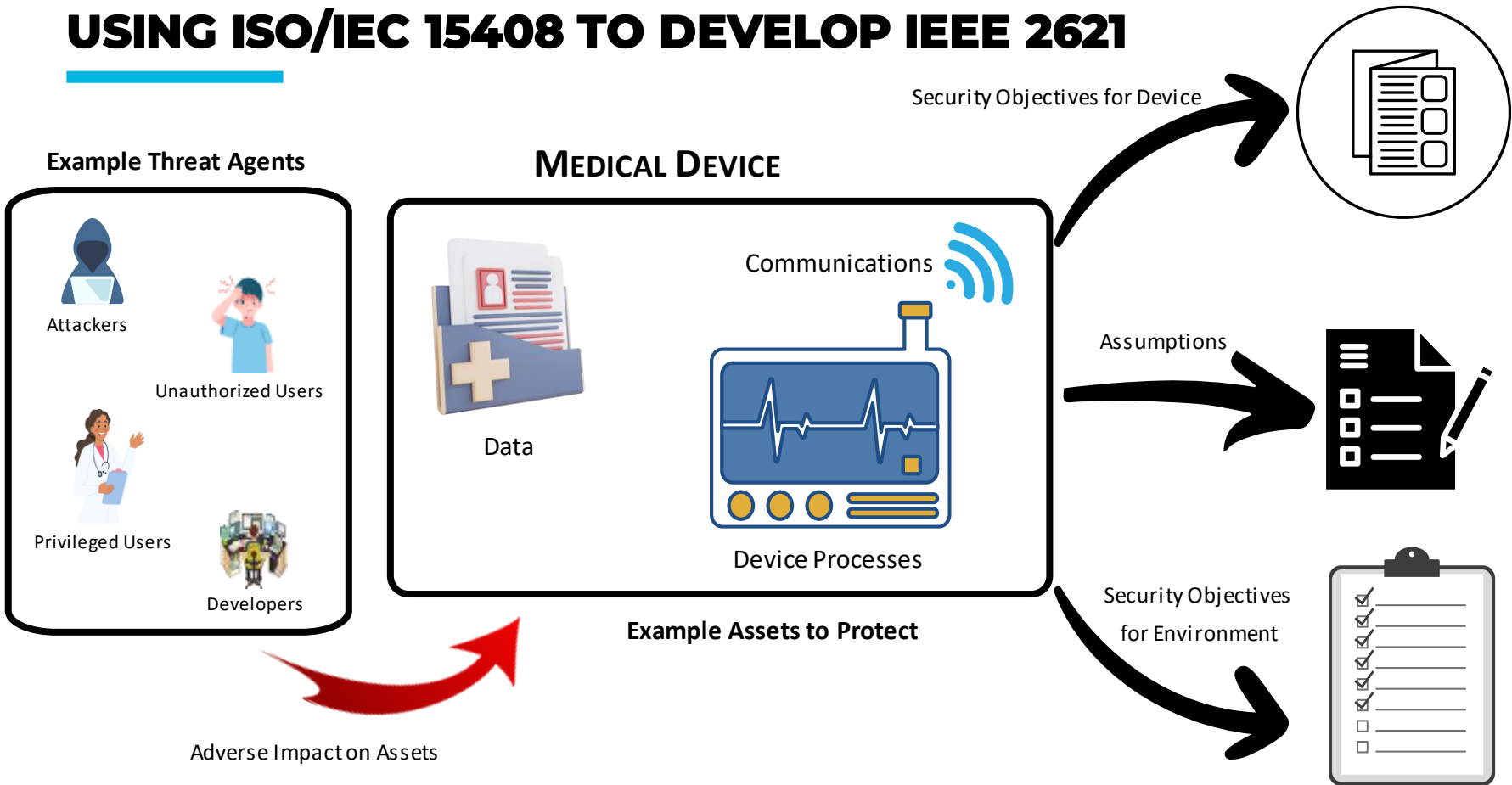
- Work on extending the scope to other medical devices will start this year
- IEEE Solution Partner Program (under development)

## Comprehensive Security Evaluation Program

**The bottom line: MDM should expect a smooth regulatory submission process!**



# USING ISO/IEC 15408 TO DEVELOP IEEE 2621



# IEEE SECURITY TARGET FOR MEDICAL DEVICES



# IEEE 2621 MULTI-PART STANDARDS

- **Approved IEEE standards as of March 2022**
  - The IEEE 2621 standard uses the Common Criteria (CC) program as a basis for its security functional and assurance requirements; conforms to the requirements of ISO 15408-1,2,3
  - Designed to be applicable to **all medical devices**, currently focused on connected diabetes devices
    - Examples: BGM, CGM, Insulin Pump, Insulin Pen, Closed Loop System/AID system,...
- **IEEE 2621.1- Framework for a connected electronic product security evaluation program**
  - Assurance Levels:
    - Basic Assurance Package - Manufacturer self-test
    - Enhanced-Basic - Testing by authorized test lab. Represents commercial best-practices.
    - Moderate - Testing by authorized test lab. Represents advanced security.
  - Lab Accreditation, Certification Criteria and Assurance Maintenance
- **IEEE 2621.2- Security requirements and protection profile**
  - Security threats/risks and functional requirements that counter these threats
  - Protection profile
- **IEEE 2621.3- Guidance for mobile devices in diabetes control contexts**
  - Ex. Usage of applications on smartphones to control insulin injection levels

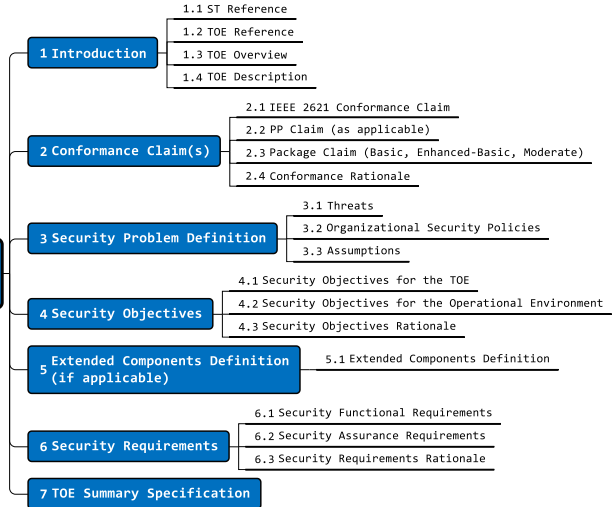
# IEEE STANDARD EVALUATION REPORT

## Manufacturer Submission to Test Lab

- Security Target documentation
- Product security flaw remediation process(es)
- An attestation signed by a Manufacturer authority



Wireless Diabetes Device Security Target



## Evaluation Result: Standard Report submitted to IEEE

Work Unit	Evaluation Requirement	Expected Results	Status	Rationale/Reference(s)/Comment(s)	Result
ASE_SPD.1-1	The Evaluator shall check that the security problem definition describes the threats.	Threat T.NETWORK identified correctly	TBD		TBD
		Threat T.PHYSICAL identified correctly	TBD		
		Threat T.BAD_SOFTWARE identified correctly	TBD		
		Threat T.BAD_PEER identified correctly	TBD		
		Threat T.WEAK_CRYPTO identified correctly	TBD		
ASE_SPD.1-2	The Evaluator shall examine the security problem definition to determine that all threats are described in terms of: (1) a threat agent	If ASE_SPD.1-1 is satisfied, then this work activity too is satisfied	TBD		TBD
		The Evaluator shall examine the security problem definition to determine that all threats are described in terms of: (2) an asset	TBD		
		The Evaluator shall examine the security problem definition to determine that all threats are described in terms of: (3) an adverse action	TBD		

Result:  
Pass,  
Fail,  
N/A,  
TBD

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# CYBERSECURITY ECOSYSTEM FOR INDUSTRY

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- **IEEE certification will help you smooth out the FDA submission process and will increase chances of product approval.**
  - Test Plans based on the 2621 standard and Inspection Checklists on AAMI TIR57 and IEC 8000-1-5
- **Authorized Test Labs, Certificates, Registry**
- **Solution Partner Program (under development)**
- **Extension to other medical devices will start after Pilot completion**

Contact IEEE if you are interested in any of the above: [medcyber@ieee.org](mailto:medcyber@ieee.org)

## **IEEE Conformity Assessment Program (ICAP)**

<https://standards.ieee.org/products-programs/icap/programs/p2621-series-of-standards/>



# Thank You!

## QUESTIONS?

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### IEEE CONFORMITY ASSESSMENT PROGRAM

TED OSINSKI  
PROG. MGR., CONFORMITY ASSESSMENT  
TED.OSINSKI@IEEE.ORG

### IEEE CONFORMITY ASSESSMENT PROGRAM

RAVI SUBRAMANIAM  
DIRECTOR, SA BUSINESS DEVELOPMENT & CONFORMITY ASSESSMENT  
R.SUBRAMANIAM@IEEE.ORG

[medcyber@ieee.org](mailto:medcyber@ieee.org)

