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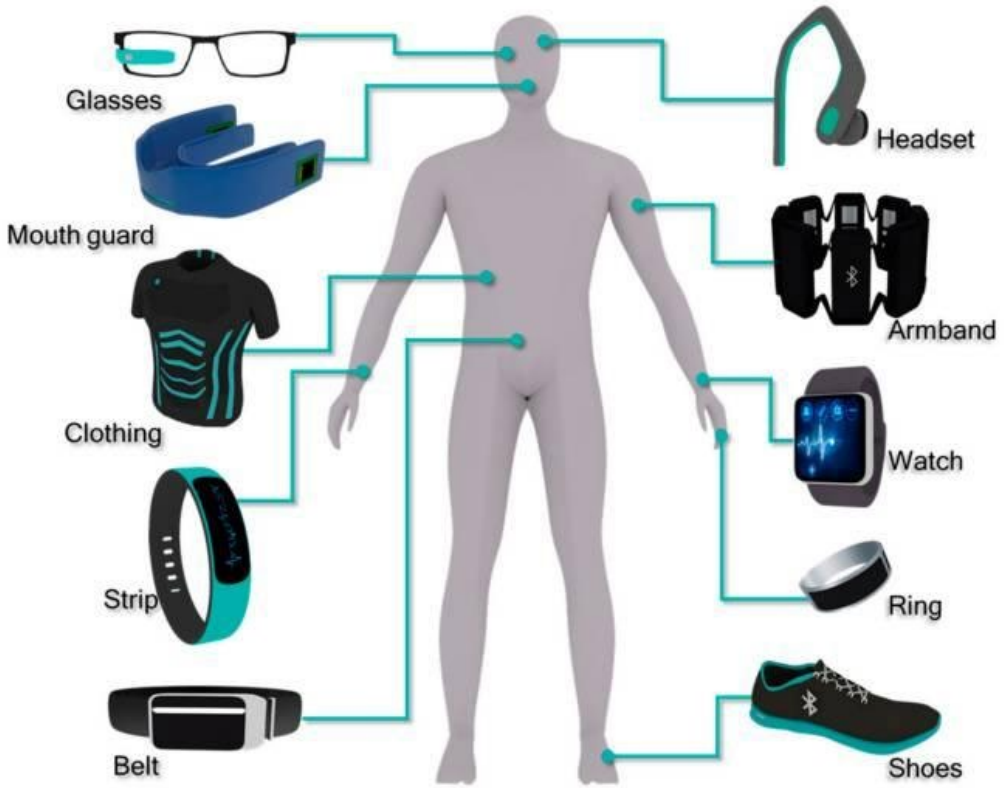
REGULATORY ISSUES IN THE DEVELOPMENT OF WEARABLE DEVICES

Salvatore Bianco MD
AKROS BIOSCIENCE SRL



Remote Patient Monitoring

Fitness and Activity Tracking

Cardiac Health Monitoring

Diabetes Management

Sleep Apnea Diagnosis

Pain Management

Medication Adherence

Fall Detection and Elderly Care

Mental Health Monitoring

Clinical Research and Trials

Pregnancy Monitoring

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GROWING MARKET

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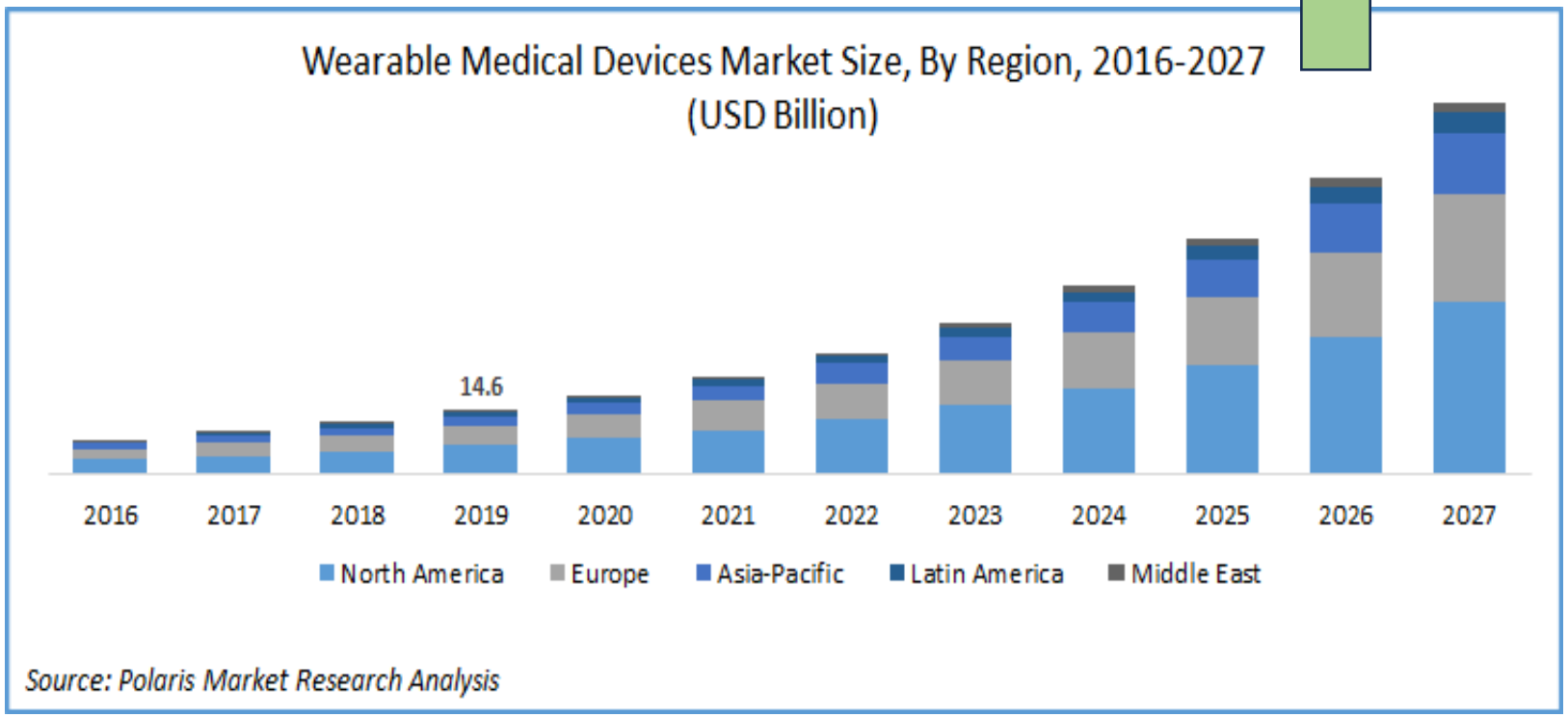
Extim. Annual Growth Rate
+ 24.8%



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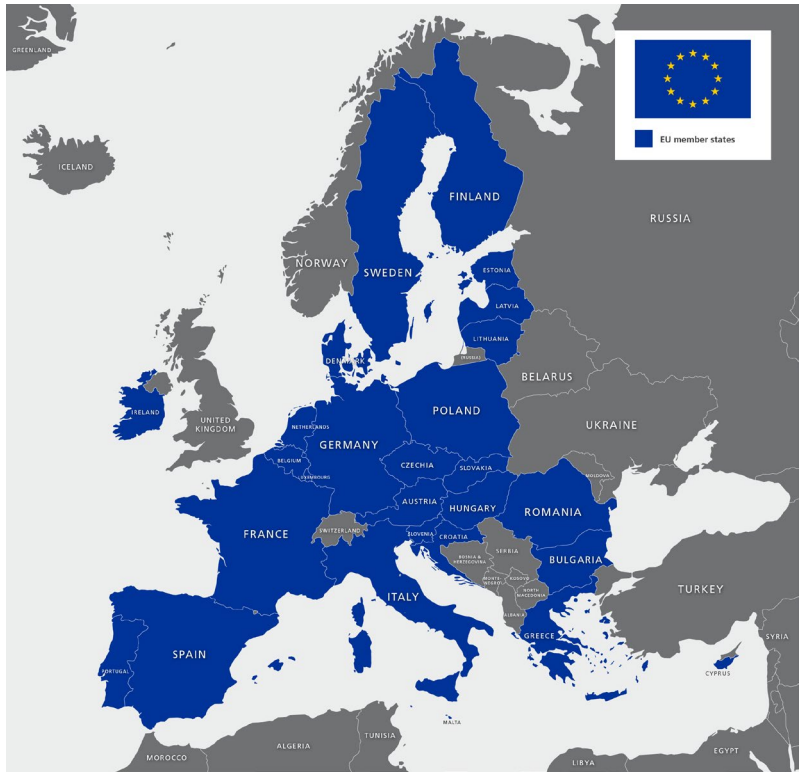
LIMITING FACTORS IN EU



1. Regulatory Hurdles
2. Reimbursement Challenges
3. Data Privacy Concerns
4. Healthcare Fragmentation
5. Limited Interoperability
6. Patient Acceptance
7. Cost Constraints
8. Limited Clinical Evidence

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REGULATORY HURDLES

Significant, especially for academy and start-ups for lack of staff with expertise in dealing with Competent Authorities

TIME

COST

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FIRS STEP: INSIGHT

Device

Wellness app?

Medical Device?

Business model

Technological provider?

Business partner?

Manufacturer?
(i.e. CE mark holder)

DEFINITION (EU)

[…] any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer […] for one or more of the following specific medical purposes: — diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,[…]and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body […]

REG 2017/745

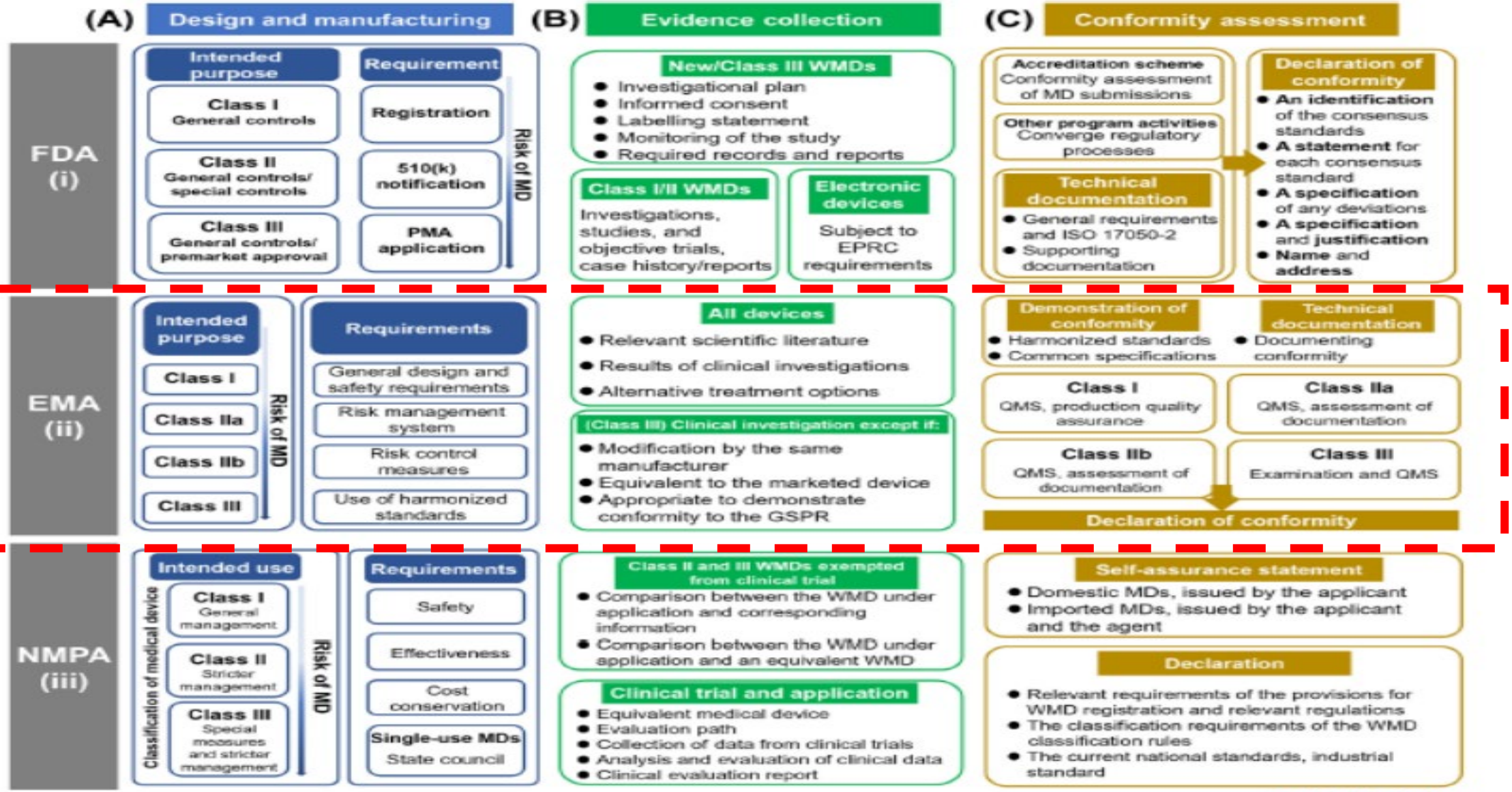
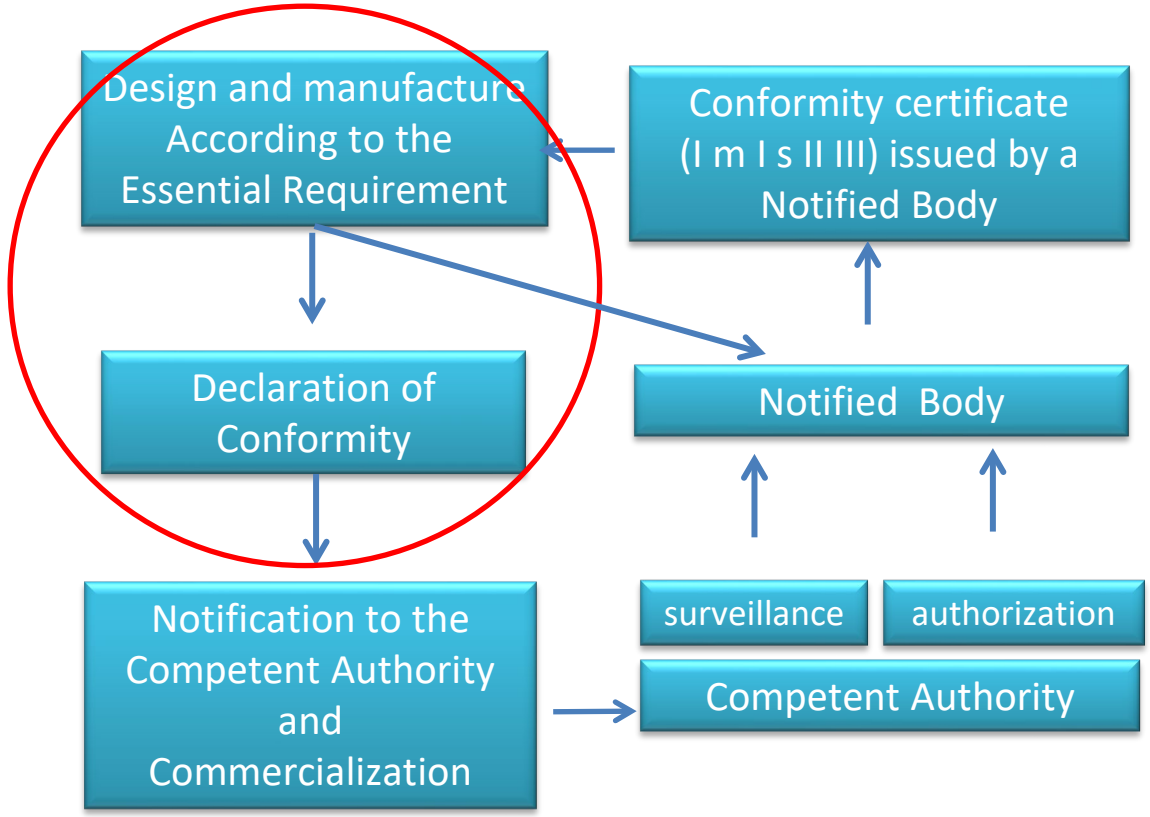


Figure 1. Regulatory Approval Considerations in Wearable Medical Devices (WMDs). (A) Design and manufacture, (B) evidence collection, and (C) conformity assessment in (i) the FDA, (ii) the European Medicines Agency (EMA), and (iii) the China National Medical Product Administration (NMPA). Abbreviations: EPRC, Electronic product radiation control; GSPR, general safety and performance requirements; MD, medical device; PMA, premarket approval; QMS, quality management system.

MEDICAL DEVICE



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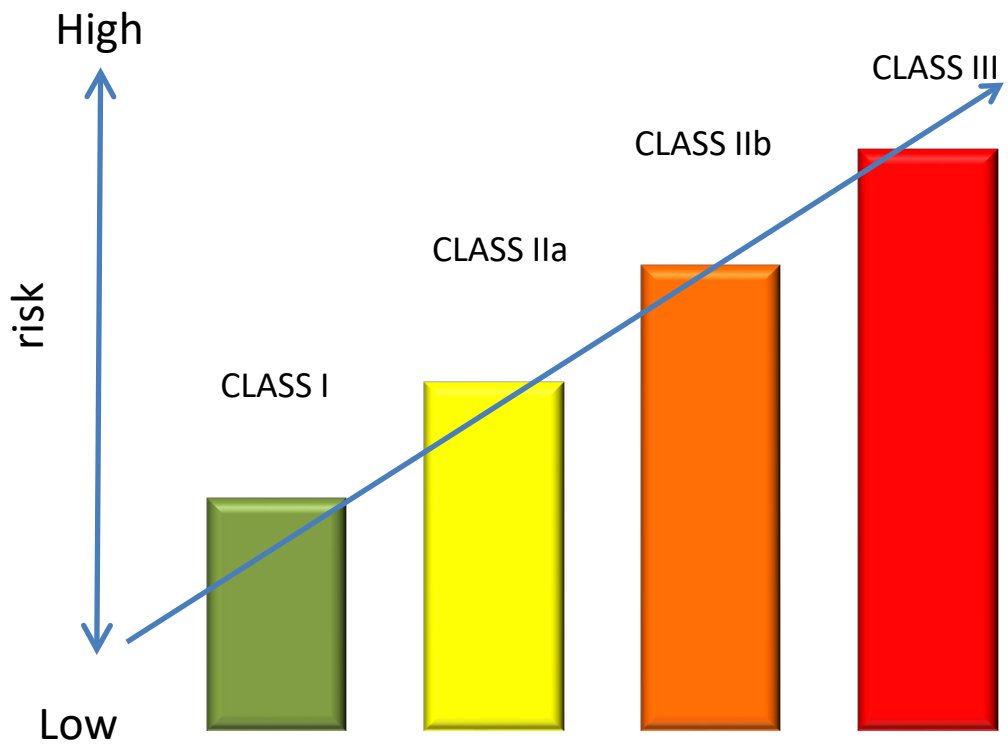
CLASS OF RISK



DEFINES THE

CONFORMITY PROCEDURE

Potential to cause harm (directly or indirectly)

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EXAMPLES

Example I

Apple Watch Series 4, identified as a Class II WMD, has been launched for monitoring the electrocardiogram and the detection and notification of an irregular heart rhythm. Around 600 subjects were tested in clinical trials, where 99.6% specificity for sinus rhythm and 98.3% sensitivity for atrial fibrillation were demonstrated.

Example II

HeartGuide™ is a noninvasive Class II WMD that monitors human blood pressure in the form of a wristwatch, which has been innovated by Omron Healthcare. It features tracking and management of the user's blood pressure up to 100 times as well as real-time monitoring of activity for up to 7 days to prevent stroke, heart failure, and sudden cardiac death.

Jang et al. Biotechnology, 2019,

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INTENDED PURPOSE VS MEDICAL INDICATION

Intended purpose is basically what the device does, e.g., record cardiac activity.

Medical indication is the medical condition in which the device is to be used, e.g., detecting episodes of paroxysmal atrial fibrillation

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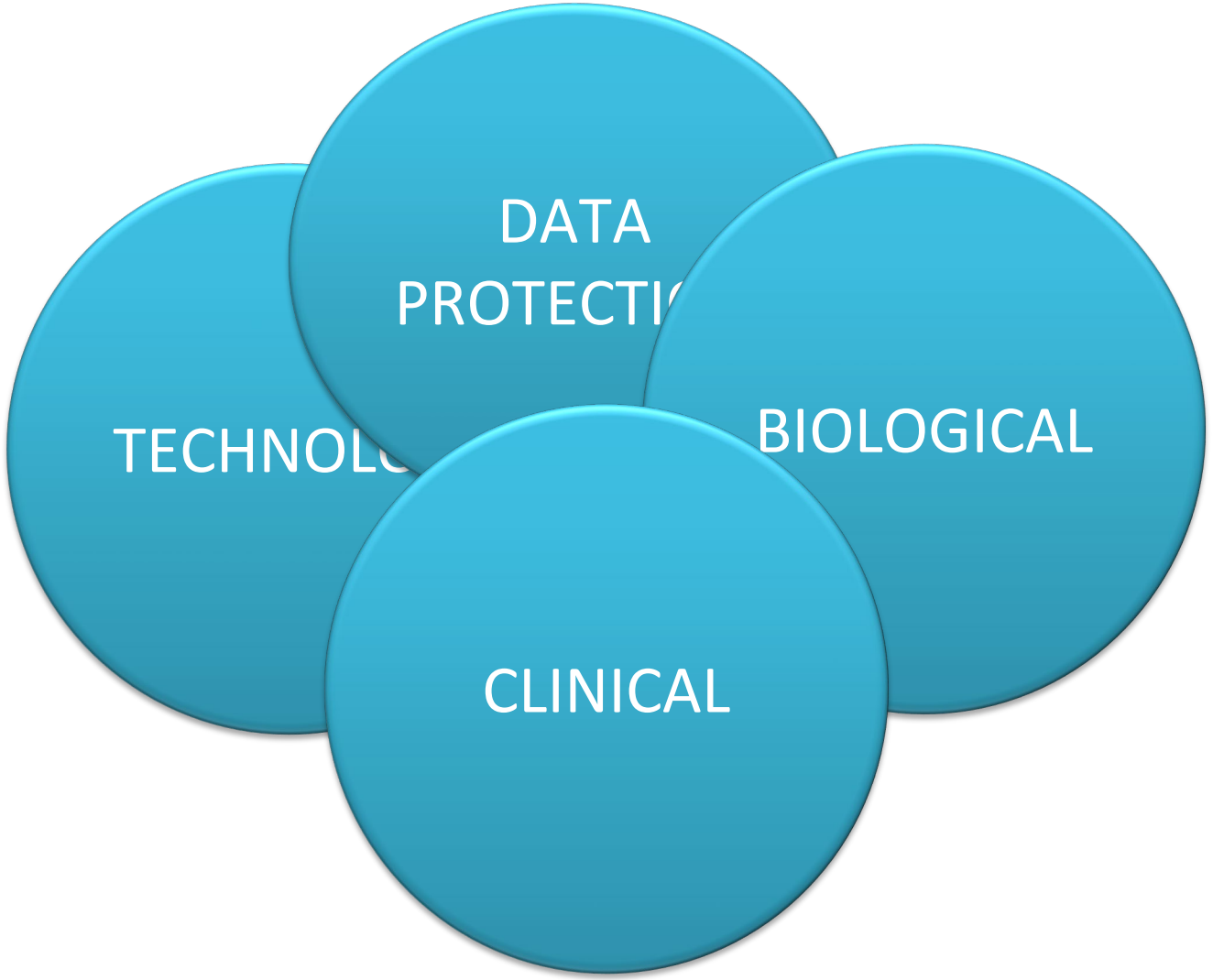
CONFORMITY: A MULTIFACETED CONCEPT



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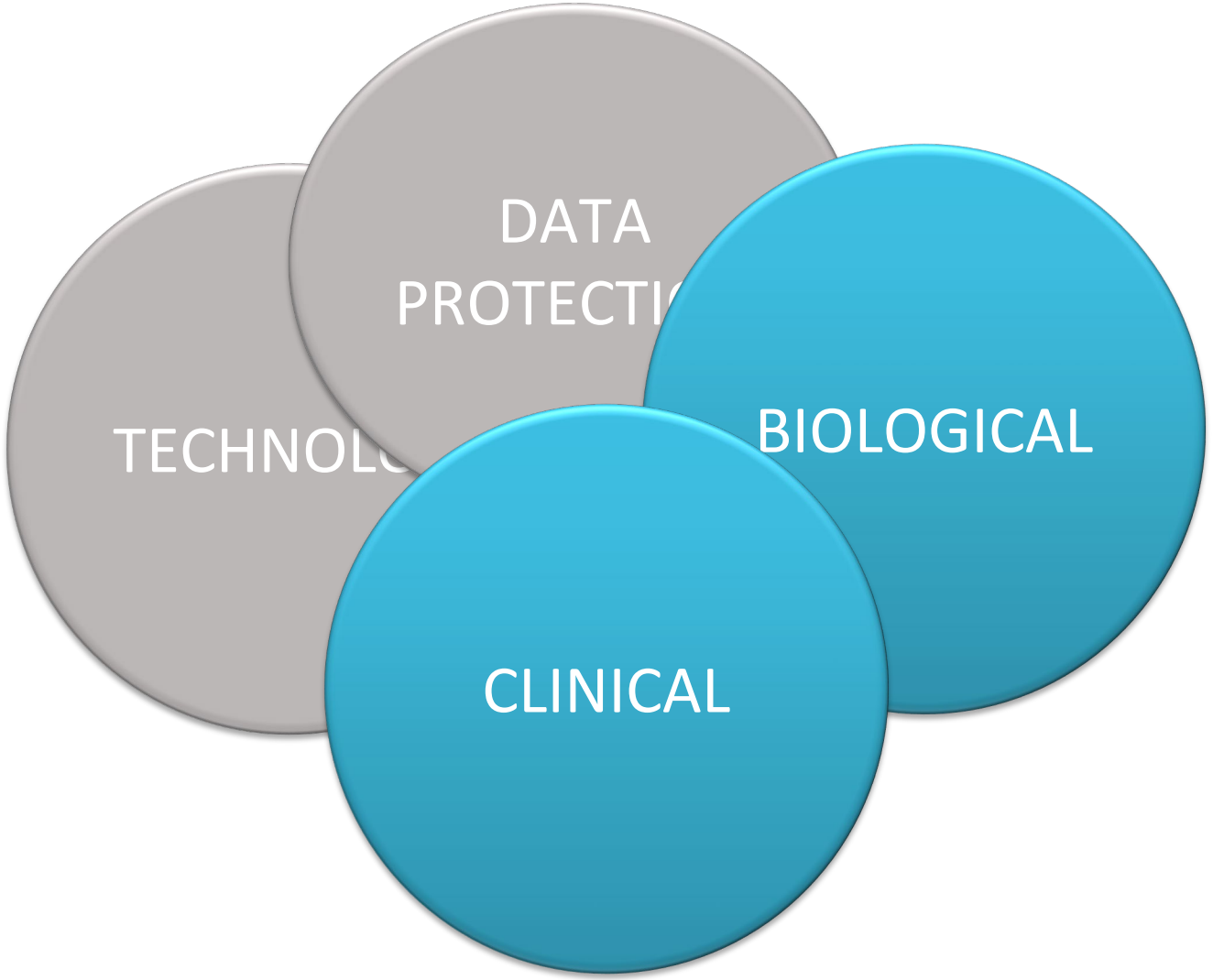
CONFORMITY: A MULTIFACETED CONCEPT



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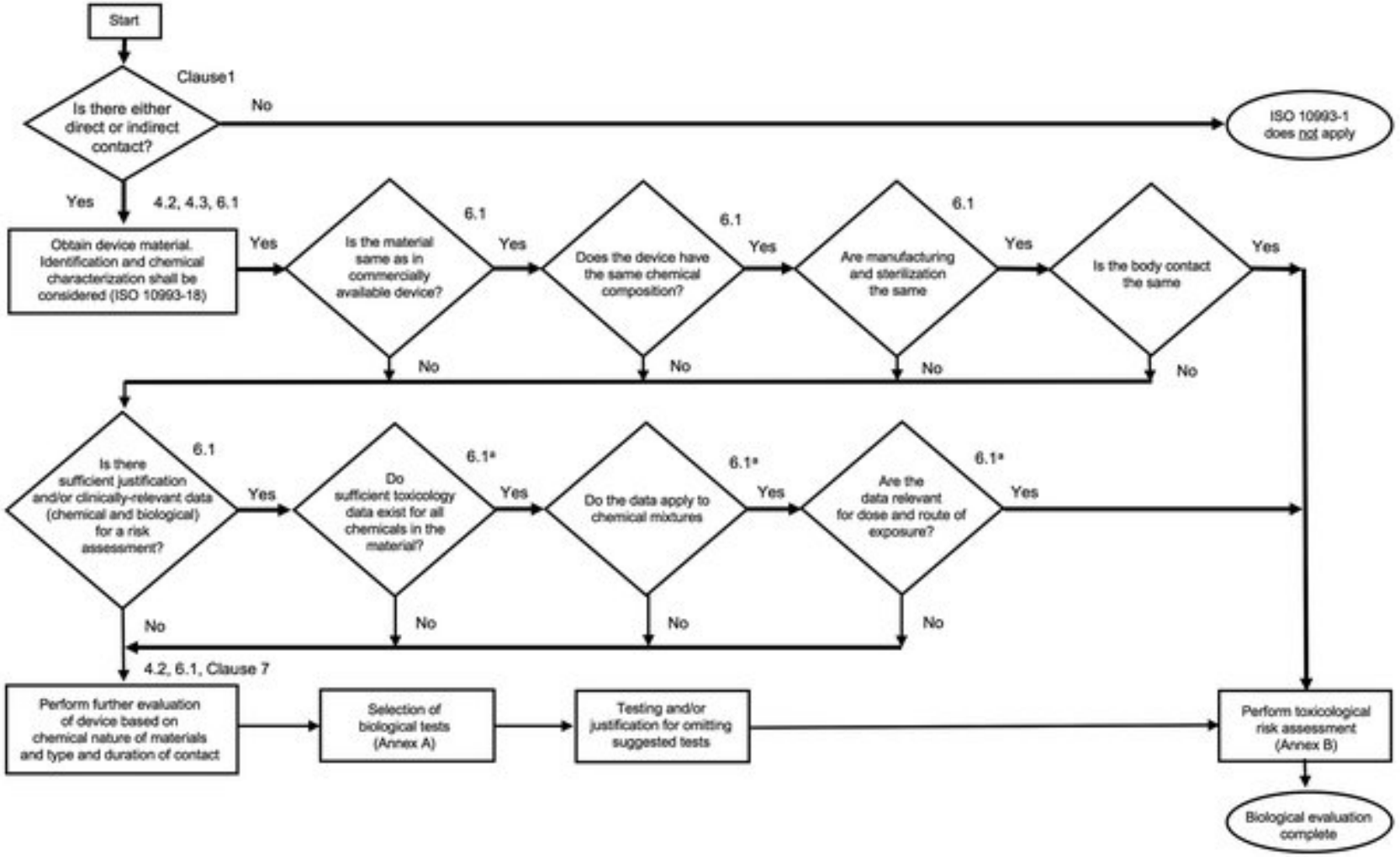
BIOLOGICAL EVALUATION

Biological evaluation primarily pertains to the assessment of the **biocompatibility** of all materials that come into contact with the end user, but also possibly with operators.
The assessment of biocompatibility is governed by the **ISO 10993** set of guidelines

BIOCOMPATIBILITY

the ability of a material to perform with an appropriate host response in a specific application

BIOLOGICAL CONFORMITY



ISO 10993-1 2009 (withdrawn) the guideline in force is ISO 10993-1 2018

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CLINICAL EVALUATION

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CLINICAL INVESTIGATION REGULATED BY ISO 14155: 2020

Assessment of the **performance** and **safety** of the device
through a series of tests that range from simple
accuracy tests to a reference device to
full-fledged clinical investigations

CLINICAL EVALUATION ACCORDING MEDDEV 2/7.1 r4

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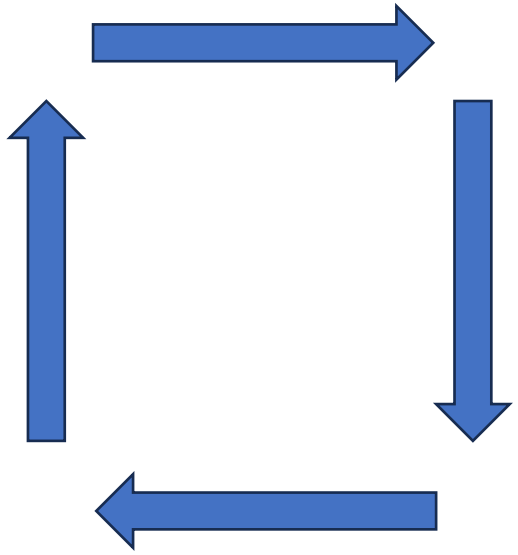
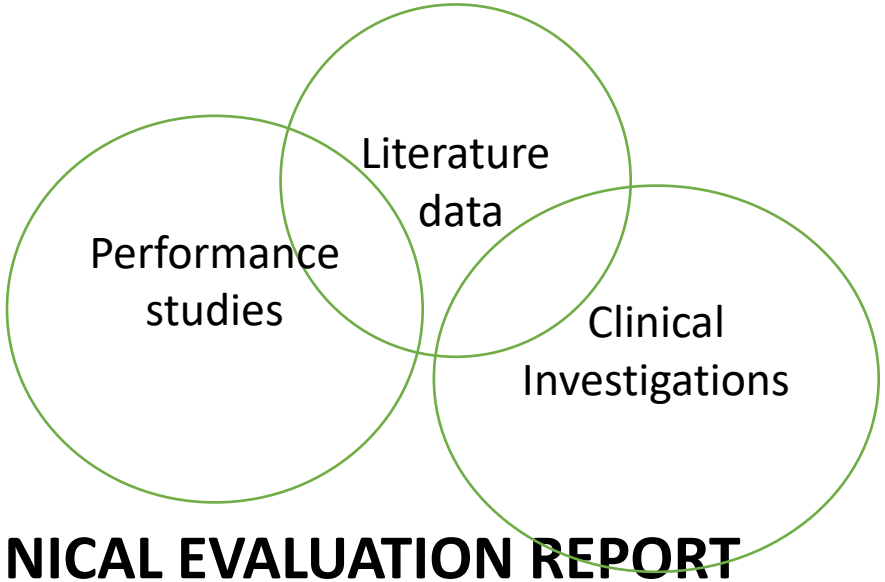
CLINICAL EVALUATION
AN ITERATIVE PROCESS

Risk Analysis

CLINICAL EVALUATION PLAN





CLINICAL EVALUATION REPORT

POST MARKET SURVEILLANCE

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CONCLUSION

DEFINTION OF THE BUSINESS MODEL AND COMPANY AIMS

DEFINITION OF THE REGULATORY FRAMEWORK

DEFINITION OG THE REGULATORY PATHWAY

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GRAZIE !

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