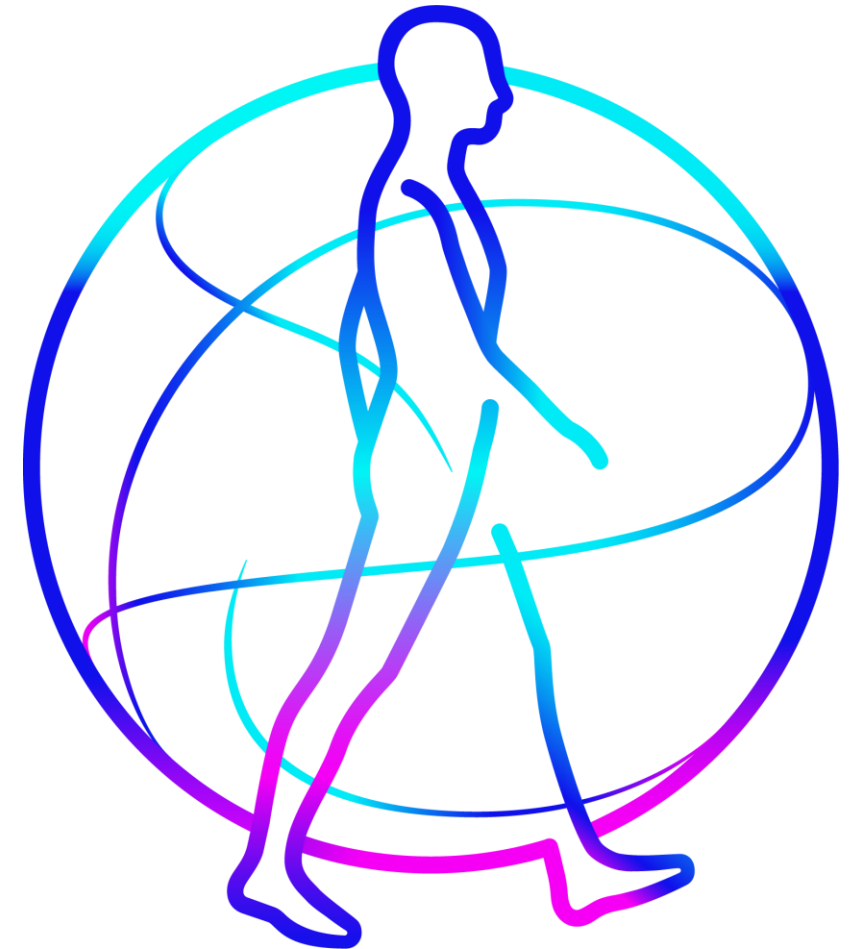


Medtronic

Engineering the extraordinary

**L'acquisto di dispositivi medici alla luce del nuovo regolamento:
modalità applicative, criticità, soluzioni**

L'esperienza di
un Operatore Economico



6 aprile 2023

Fulvia Meroni, Regulatory Affairs Manager, Medtronic Italia S.p.A.

Today

- Medtronic and EU MDR
- How we organized for MDR ?
- Who are we working with ?
- What is working well ?
- What are our main challenges ?
- Concluding remarks





76M+

In the past year, Medtronic therapies improved the lives of 76 million+ people. That's **two people every second** of every hour of every day – and counting.

Engineering the extraordinary

150+
countries

95K+
employees

80
manufacturing
sites

38
labs and research
development sites

239
clinical trials
last year

\$2.7B
in R&D investments
last year

12.9K+
scientists
and engineers

49,967
active
patent matters

Our dedication to transforming lives starts here

Better
outcomes for
our world

Life-transforming
technologies

Experiences
that put
people first

Insight-driven
care

Beyond products: Integrated health solutions (IHS)

We partner with hospital management and medical leaders to transform care pathways and clinical operations, with a shared goal of:

- Improving efficiency and outcomes
- Increasing patient and staff satisfaction
- Optimizing cost

With our extensive experience across and within regions, we provide proven and highly effective solutions that can be quickly tailored to providers' specific needs and generate value now – and for the future.

Positive impact on complex and challenging conditions

70+

conditions in the human body
treated with our therapies

2

people every second
have their lives improved –
and counting

Public-private partnerships

Increasing patient access in multiple communities aligns with the core of our Mission. These public-private partnerships – with outcome-oriented business models – create mutual benefits by making the most of Medtronic skills, expertise, and assets through the appropriate transfer of risk. They drive our globalization strategy and actively contribute to the international push for universal health coverage. With jointly defined objectives, they address health system challenges efficiently by increasing access to therapy innovation, raising quality, and delivering improved outcomes.

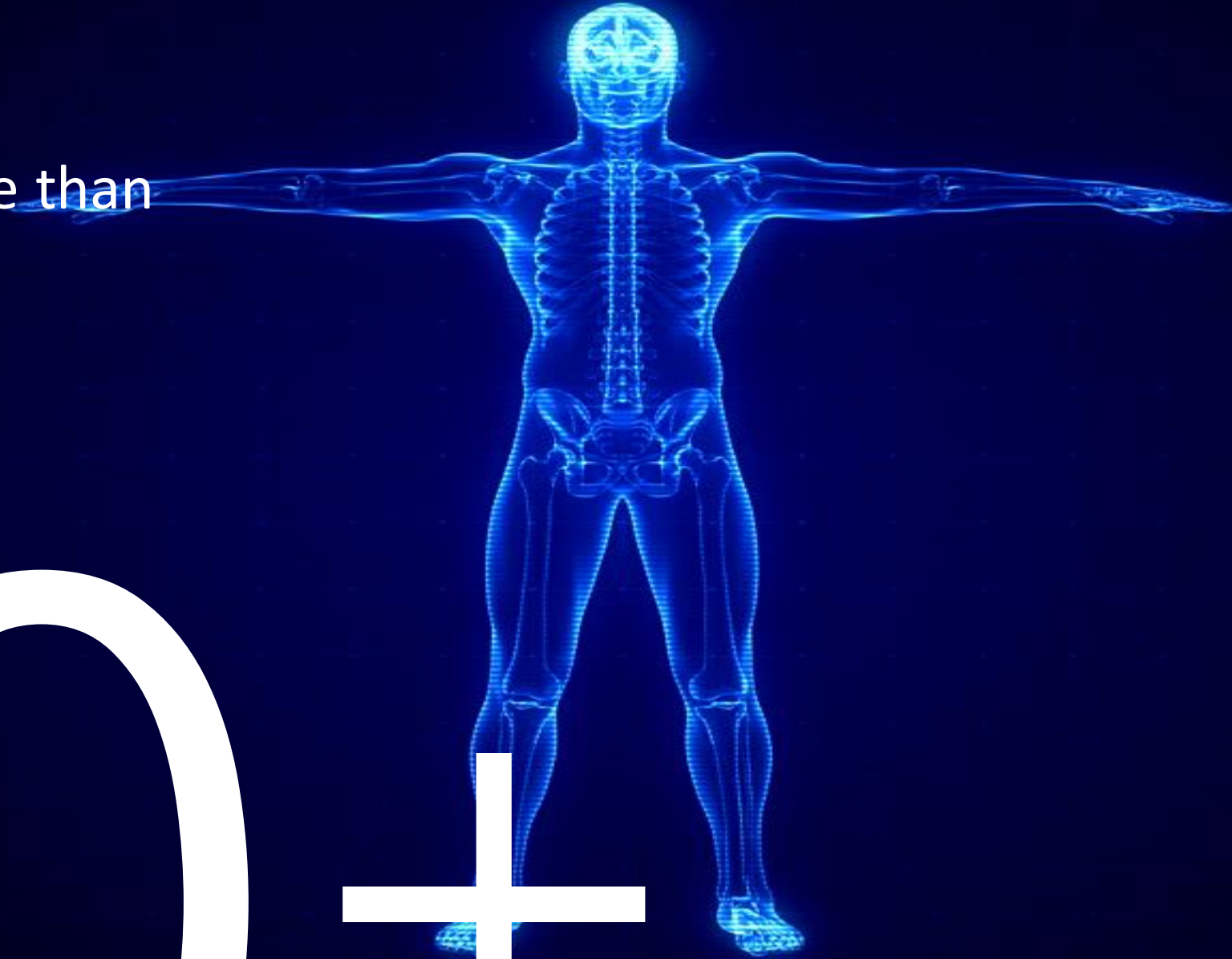
Learn more at [Medtronic.com](https://www.Medtronic.com)

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Medtronic

Engineering the extraordinary

Our life-transforming
technologies treat more than
70 conditions



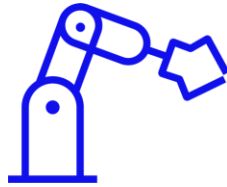
70+

Our therapies and solutions span four portfolios to treat more than 70 conditions in the human body



Cardiovascular

[Learn more](#)



Medical Surgical

[Learn more](#)



Neuroscience

[Learn more](#)



Diabetes

[Learn more](#)

Medtronic

Today, we are engineering the extraordinary to treat more than 70 conditions.

Cardiovascular



Cardiac Ablation Solutions

- Persistent atrial fibrillation
- First line indication paroxysmal atrial fibrillation
- Non-atrial fibrillation arrhythmias

Cardiac Surgery

- Beating heart bypass surgery
- Perfusion
- Surgical revascularization
- Extracorporeal life support
- Surgical valves for aortic, mitral, and tricuspid valve diseases

Mechanical Circulatory Support

Cardiac Rhythm Management

- Bradycardia
- Tachycardia
- Sudden Cardiac Arrest (SCA)
- Arrhythmia diagnostics
- Infection control for implanted devices
- Remote monitoring
- Heart failure
- Cardiac resynchronization therapy

Peripheral Vascular Health

- Carotid artery disease
- Chronic venous insufficiency
- End-stage renal disease
- Peripheral artery disease
- Deep venous disease

Structural Heart and Aortic

- Aortic valve disease
- Mitral valve disease
- Pulmonary valve disease
- Tricuspid valve disease
- Aortic abdominal aneurism (AAA)
- Thoracic aortic aneurysm (TAA)

Coronary & Renal Denervation

- Hypertension
- Coronary artery disease

Cardiovascular Diagnostics and Services

- Stroke
- Syncope
- Suspected atrial fibrillation
- Atrial fibrillation management
- Cardiac arrhythmias

Diabetes



- Type 1 diabetes
- Type 2 diabetes

Medical Surgical



Gastrointestinal

- Colorectal polyps
- GI bleeding
- GERD
- Barrett's esophagus
- Liver tumors
- Motility disorders
- Hemorrhoids

Patient Monitoring

- Blood oxygen management
- Respiratory compromise
- Perioperative complications

Surgical Robotics

- Urologic
- Gynecologic
- General surgery (alimentary canal & abdominal)

Renal Care Solutions

- Acute kidney injury
- Chronic kidney disease
- End stage renal disease

Respiratory Interventions

- Respiratory failure

Surgical Innovations

- General Surgery
- Colorectal conditions
- Gynecologic conditions
- Obesity & metabolic health
- Hernia repair
- Wound management
- Lung health

Medtronic Care Management Services

Cranial & Spinal Technologies

- Cranial and orthopedic trauma
- Neurological disorders
- Neuro tumors
- Hydrocephalus
- Spinal and cranial tumors
- Spine trauma and deformity
- Scoliosis
- Degenerative diseases
- Herniated/bulging discs
- Spondylolisthesis
- Spinal stenosis

Pelvic Health

- Overactive bladder
- Non-obstructive urinary retention
- Fecal incontinence

Neurovascular

- Acute ischemic stroke
- Hemorrhagic stroke

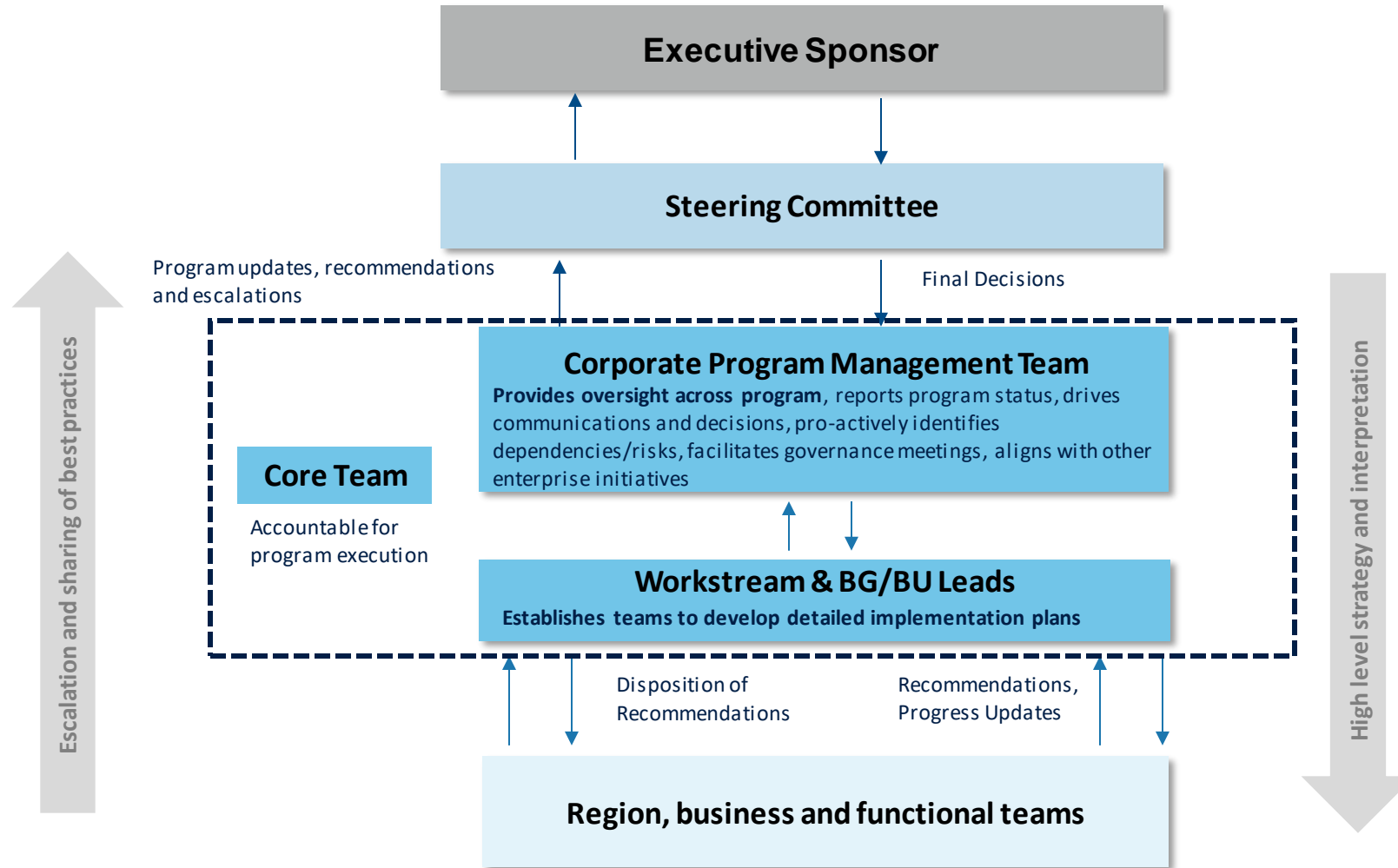
Neuromodulation

- Parkinson's disease
- Epilepsy
- Essential tremor
- Cancer pain
- Chronic pain
- Severe spasticity
- Vertebral compression fractures

Ear/Nose/Throat

- Chronic rhinosinusitis (CRS)
- Head and neck cancer
- Skull base tumors

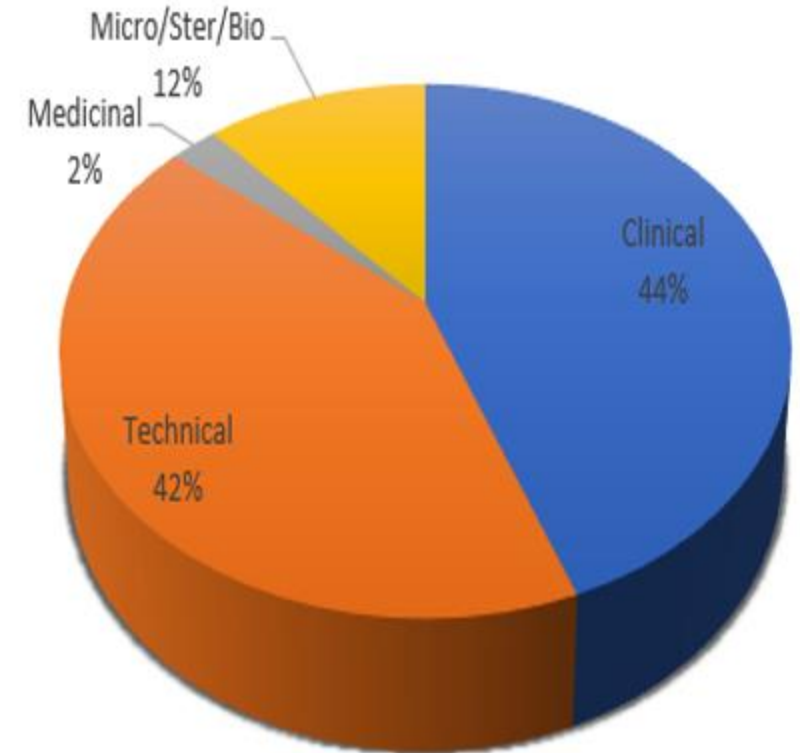
How we organized for EU MDR ?



Who are we working with ?

- Work with **10 Notified Bodies**
- **Actively filing** under MDR since 2019
- **Four Notified Bodies** cover **90%** of our portfolio
- **Time-to-certification varies** across all device categories & Notified Bodies
- Submission Files are **10x** volume vs MDD
- **Volume** of questions much **higher** than previous experience under MDD

Breakdown of the Notified Body deficiency types for a typical OU



What is working well for us ?



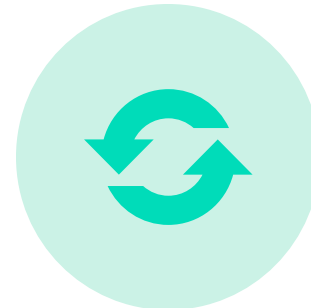
Lesson Learned: Pilot Submissions & Sharing of best practices within the organisation



Interactive: Regular interactions with Notified Bodies



Enhanced **Submission tracking** and status reporting/visibility



Scheduled reviews: Notified Bodies schedule reviews at start and through deficiency cycles.

What are our main challenges ?



Notified Body **Capacity**

Predictability of review process/timelines

Medicinal Reviews - capacity & review times

Maintaining outside EU registrations - Historical reliance on CE Mark

Minimizing **Supply Disruptions**

Impact **Innovation** in Europe

Conclusions

- We want to see MDR done
- We are seeing progress but significant distance to go
- We need to keep Patient Access to the forefront
- Patients deserve access to what they currently have today at a minimum...**and** the latest innovations.
- We need predictability in the certification process



