WHITEPAPER

for the further development of the MDR and IVDR

The initial situation

- Complex and non-transparent regulations
- Missing regulations for orphan devices, niche products and fast track
- Difficult development and market introduction of new products in Europe
- Declining attractiveness of the CE mark
- Foreseeable shortage of medical products
- Slowed pace of innovation

Our goal with the further development

- A solid, transparent and predictable legal framework for placing on the market of medical devices and in vitro diagnostic medical devices
- A high level of safety and health protection
- Promotion of innovation
- A structure that takes overall responsibility
- Compliance with the principles of good administration

5 Areas of action

1 SUPPLEMENTATION OF THE CURRENT REGULATORY SYSTEM

Fast-track procedures similar to other legislative areas for

- Innovative products
- Orphan devices and Diagnostics for rare diseases
- Niche products with a proven track record

2 INCREASE THE EFFICIENCY OF THE SYSTEM

Consistent implementation of the principles of good administration

- Predictable deadlines and costs of regulatory procedures
- Equal access to the regulatory system for everyone
- Increased transparency of certification processes, also through digitalisation
- Effective legal remedies against market access decisions
- Better coordination of parallel and national legislation

3 REFORM OF THE FIVE-YEAR RE-CERTIFICATION CYCLE

- Abolish the five-year limited expiry date of the certificates.
- More efficient and risk-based certification, based on post-market data.
- IVDR: self-certification of low-risk class (Class B) devices to reduce system burden and eliminate bureaucratic reports with no patient benefit

4 IMPROVING INTERNATIONAL COOPERATION

- Regain international reputation of CE marking
- Strengthen EU involvement in the MDSAP programme for QM systems
- EU MRA (Mutual Recognition Agreement) with Switzerland and UK

5 CENTRALISATION OF RESPONSIBILITY

- Establish a central accountable administrative structure
- Harmonise and centralise notification and surveillance of Notified Bodies across Europe
- Establish SME office at EU level

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Full Whitepaper
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