Meditix Solutions

Global Regulatory Consulting Services

Dr. Klinisch research

Customized Clinical Consulting Services

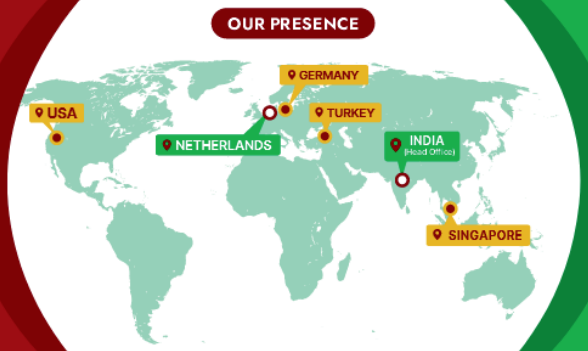
One Stop Solution for your Medical Device Regulatory & Clinical Needs

Regulatory

- Documentation
- Certification
- Training

Compliance

- Device Testing
- EMI & EMC Testing
- Product Particular Standards



Clinical

- Design Validation
- Clinical Evaluation
- Post Market Clinical Follow-up

Research

- Clinical Trial
- Biostatistics
- Publication

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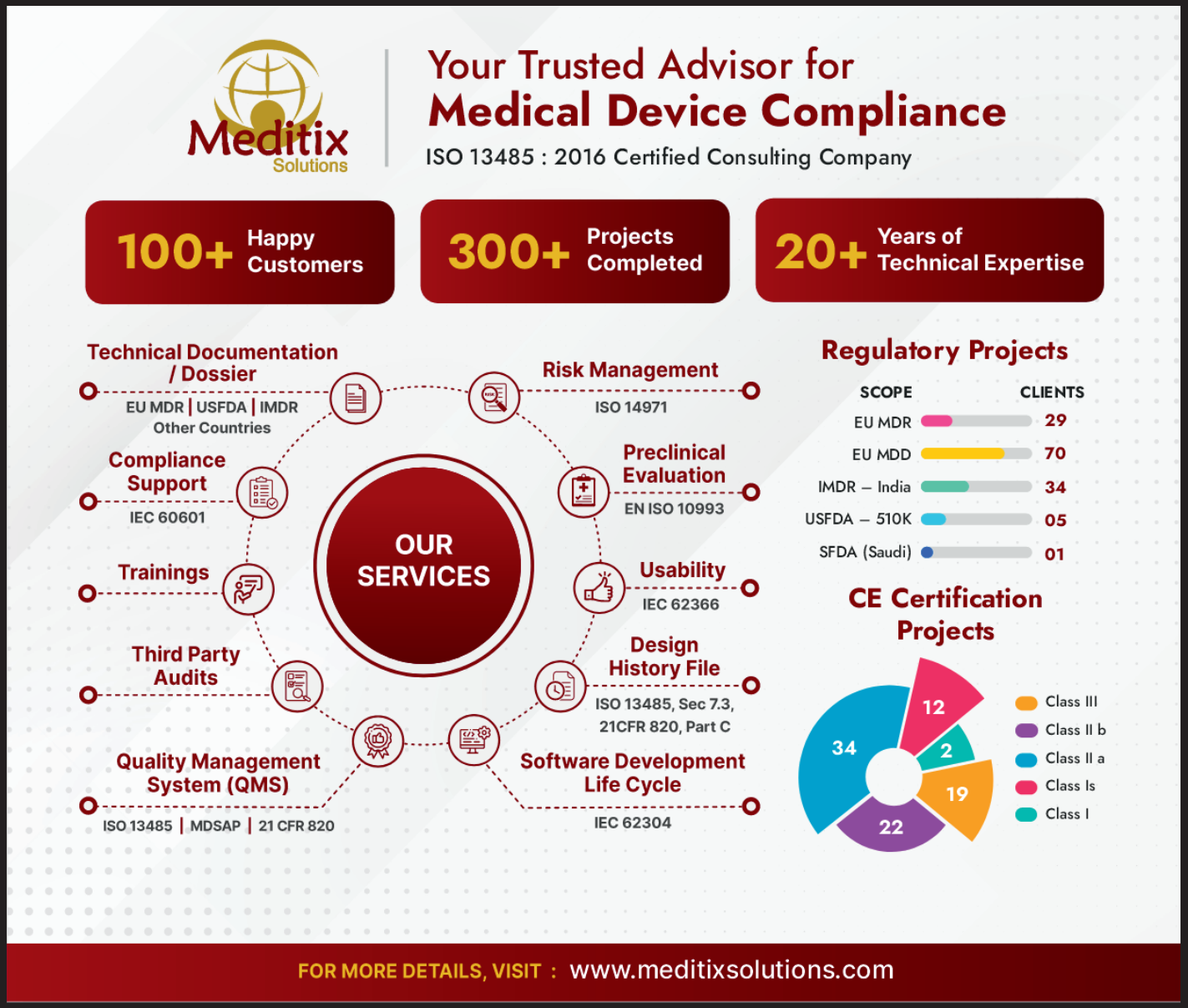
380cm (W) x 240cm (H)



284cm (W) x 240cm (H)

Our Services

Clinical Evaluation Report
EU MDR 2017/745, Annex XIV Part A

Clinical Investigation
EU MDR 2017/745, Annex XV & ISO 14155 : 2020

Post Market Clinical Follow Up
EU MDR 2017/745, Annex XIV Part B

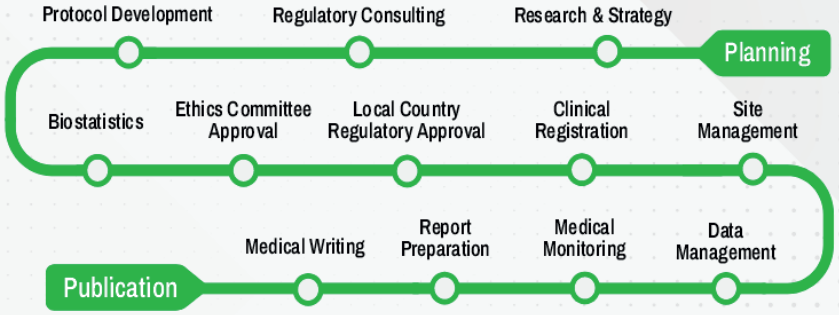
Design Validation
ISO 13485 : 2016 Clause 7.3.7 & Product STD requirements

Periodic Safety Update Report
EU MDR 2017/745, Article 86

Summary of Safety & Clinical Performance
EU MDR 2017/745, Article 32

Why Choose Dr. Klinisch?

We are with you in the journey of your Medical Device



Dr. Klinisch research

Contract Research Organization

PMCF Studies
110+ COMPLETED
60+ ONGOING

Publication
5+ COMPLETED
15+ ONGOING

Clinical Investigation
20+ COMPLETED
5+ ONGOING

Design Validation
5+ SUCCESSFUL

284cm (W) x 240cm (H)