GARDNER LAW

MEDTECH | PHARMA

EU Medical Device Regulation (MDR)

Thursday, November 7, 2019
10.30 AM – 11.15 AM EST
9.30 AM – 10.15 AM CST
8.30 AM – 9.15 AM MST
7.30 AM – 8.15 AM PST

Presented by
Dr. Cord Willhöft, LL.M., Partner, Life Sciences, Fieldfisher
Jim Murray, M.Sc., Consultant, Gardner Law

The Depot, Minneapolis, Minnesota

GARDNER LAW fieldfisher

Agenda

- Speaker bios
- New obligations
- Responsible person(s)
- Notified body concerns
- MDD vs. MDR
- An auditor’s perspective

Jim Murray, M.Sc.

Bio

- Operations and Quality expert
- Consultant, Gardner Law
- Vice President, Stillwater MedTech Consulting
- Adjunct Professor, University of St. Thomas Graduate School of Engineering – Design and Manufacturing of Medical Devices
- Past industry roles include Plant Manager and VP

Audience Participation

Show of Hands:

1. Which of your organizations already market medical devices in the EU, (presumably with an MDD-based CE mark)?
2. How many of your organizations have an active project to update their systems and submissions to comply with the EU MDR?
3. How many of you are concerned about your organization's understanding or ability to comply with the MDR and what that might mean regarding your ability to sell in the EU?

Key Messages

1. New “Normal” for investment required to market in the EU

2. Easy to:
   - Over-estimate the changes needed to comply
   - Under-estimate the resources required to maintain compliance

3. Take it Seriously

GARDNER LAW

EU MDR Highlights

- "Entry Into Force" May 2017
- Compliance requirements phase in starting May 2020
- Impacts to current CE marked product depends on expiration of current MDD-based certificates
- Current CE marked products can continue to be marketed in EU until their MDD certificates expire – with important conditions:
  - No "substantial" changes to product (design or mfg process) that would require Notified Body review
  - Compliance with selected MDR requirements starting in May 2020:
    - Product Registration Requirements (UDI, SRN)
    - Post-market surveillance
    - EU Vigilance Reporting Timelines
    - Clinical Investigation Requirements
- EUDAMED launch delayed until 2022

A Range of Workload Scenarios

“Have a CE Mark”

“Need a CE Mark”

- Class III CE Marked Products
- Certs valid beyond May, 2020
- MDR-Registered Notified Body
- ISO 13485:2016 QMS Cert
- MEDDEV 2.7/1 Rev 4 Clinical Evaluation
- ISO 14971:2007 Risk Management

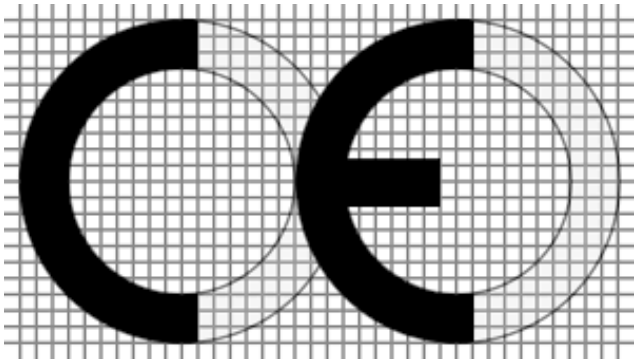
- Class III Product
- Planning to market in EU
- No CE Mark
- No EU Notified Body
- No NB-issued QMS Cert
- Insufficient data for Clinical Evaluations
- Risk Management not Compliant to ISO14971

GARDNER LAW

Need a CE Mark?

Key Actions (if your device is on the class IIb/III end of the spectrum):

1. Engage an EU MDR-Registered Notified Body and work closely with them.
2. Apply new classification rules to verify your device classifications
3. Establish an ISO 13485:2016 and ISO 14971:2007 Compliant QMS
4. Obtain a QMS Certificate of Conformance from your NB
5. Fulfill “Technical Document” Requirements of EU MDR
6. Pass EU MDR Conformance Assessment by your NB
7. Establish resources to maintain compliance – the new “normal” for access to EU markets



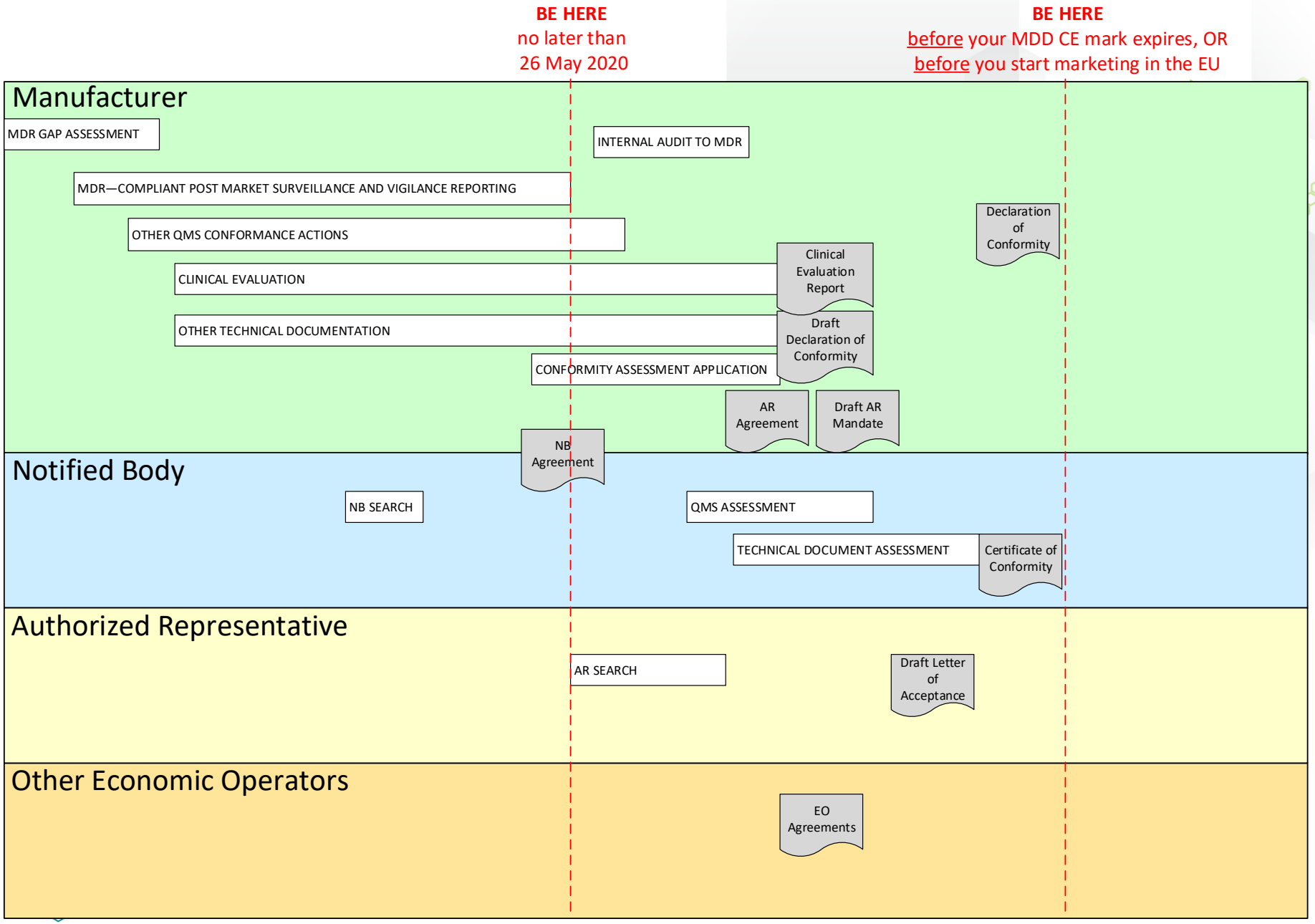
GARDNER LAW

Already Have a CE Mark?

Key Actions:

1. Make sure your Notified Body is registered for EU and work closely with them.
2. Apply new classification rules to verify your device classifications
3. Update QMS to include product registration, Post-market Surveillance, and new EU vigilance Reporting
4. Map out timelines for MDR-based CE Marks and full MDR compliance
5. Perform MDR Gap Assessments to clarify necessary QMS improvements
6. Charter and execute project to implement QMS changes
7. Establish resources to maintain compliance – the new “normal” for access to EU markets

Already Have a CE Mark?



Summary

1. A New “Normal” for investment required to market in the EU
   - Registrations and Reporting
   - Post Market Surveillance
   - Clinical Evaluations
   - Risk Management

2. Easy to:
   - Over-estimate the changes needed to comply
   - Under-estimate the resources required to maintain compliance

3. Take it Seriously
   - Update your ROI expectations for markets accessed via CE Mark
   - Get close to your EU MDR-Registered NB
   - Get help!

Thank You!

Questions?

Jim Murray, M.Sc., Vice President
Stillwater MedTech Consulting
jmurray@stillwatermedtech.com
612-810-9032 (mobile)

GARDNER LAW