Innovation challenges for orthopedic device manufacturers under the new EU MDR – A notified body perspective

Dr. Max Singh
Global Director – Orthopedic Focus Team
Phoenix (AZ/USA), 9th February 2019
# Who am I?

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<thead>
<tr>
<th>Name</th>
<th>Dr. Max Singh</th>
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<tbody>
<tr>
<td><strong>Roles:</strong></td>
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<tr>
<td>• Global Director – Orthopedic Focus Team</td>
<td></td>
</tr>
<tr>
<td>• Head Coach EU MDR within TÜV SÜD</td>
<td></td>
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<tr>
<td><strong>Employer:</strong></td>
<td>TÜV SÜD Product Service GmbH</td>
</tr>
<tr>
<td><strong>Experience:</strong></td>
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<td>• EU Notified Body representative since July 2017.</td>
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<tr>
<td>• 15 years in the medical industry, mainly in orthopedics.</td>
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</tr>
<tr>
<td>• Experience in R&amp;D, Product Management, Marketing &amp; Sales, RA</td>
<td></td>
</tr>
<tr>
<td><strong>Mobile:</strong></td>
<td>+49 171 2770860</td>
</tr>
<tr>
<td><strong>E-mail:</strong></td>
<td><a href="mailto:max.singh@tuev-sued.de">max.singh@tuev-sued.de</a></td>
</tr>
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This presentation is based on information available as of today and prepared to my best knowledge as subject matter expert.

This presentation presents my personal understanding of the medical device requirements in Europe and is not reflecting the view of TÜV SÜD PS.
Innovation in the Medical Device Industry

Large & incumbent firms

Small – and medium sized enterprises (SME)

Innovation

(>90%)
What is happening when in EU Medical Device Regulation?

- **2008**: Commission: consultation on medical device framework
- **2012**: Commission: proposal for new MDR
- **2014 Q2**: Parliament: position on MDR
- **2015 Q3**: Council position on proposed Regulation
- **2015 Q4**: Trilogue: Commission, Parliament, Council
- **2017**: MDR published on May 5, 2017
- **2020**: End of three-year transition on May 26, 2020

**Medical Device Regulation**

**Current Notification of NBs Void:**
- **26 May 2020**

**Devices falling in the scope of the MDR**
- **Compliance from:**
  - **26 May 2020**
Relevant conditions to place devices on the EU market

5 Points to consider

From 26th May 2020 no significant changes in design & intended purpose

Post-market surveillance requirements of the MDR must be fulfilled

From May 26th 2020 reporting of SAE & device deficiencies per MDR

Registrations of Economic Operators & devices per MDR

Made available or put into service until 27th May 2025
Some rules for the grace period 2020 – 2024

What happens with MDD/AIMD Certificates?

What effect does this have?

What will happen after May 2024?

What will happen with class I device that remain class I?

What will happen with reusable surgical instruments as they stay in class I?

What happens if a device is reclassified from IIa to III?
Challenges for Manufacturers

- Competence must be built
- QMS must be adapted
- Manufacturers must adjust TD and agree it with NB
- Up-classifications to be considered (e.g. spinal devices)
- Consultation procedures to be considered
- Check the clinical data – is it sufficient?
- Higher requirements on PMS – Resources available?
Do not forget the main aim of regulations

...be realistic in setting expectations

The European Medical Device Approval is getting tougher than the US FDA System

Innovation starts to go first to the US instead of coming to Europe

Does this fulfil the main aim of the European regulation towards a better healthcare system in the EU?
Do not forget the main aim of regulations

…be realistic in setting expectations

Patient benefit and safety expectations should be in focus

Continuity of state of the art healthcare system must be ensured

Innovation towards a better healthcare system must be supported

Formalistic expectations must be eliminated
Chances for big and small manufacturers

Large firms
• Take advantage of staff number
• Take advantage of existing processes
• Take advantage of existing sales channels

SME & Start-ups
• Decisions must be taken: Advantage of having short reporting lines
• Create MDR processes from scratch
• Take advantage of dedicated EU-funds (e.g. to financially support clinical investigations)

EU MDR
Get in contact with us…

Sign-up for Healthcare and Medical Devices E-ssentials, TÜV SÜD’s complimentary newsletter that delivers updates on the latest regulations and standards, at:

www.tuv-sud.com/e-ssentials

Dr. Max D. Singh
Global Director
Orthopaedic Focus Team
Global Medical Health Service
max.singh@tuev-sued.de
Phone: +49 171 2770860

Contact us:
www.tuv-sud.com
info@tuv-sud.com

Follow us on social media:
instagram.com/tuv suede
linkedin.com/company/tuv-sud
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