Medical Device Standards

Focus: AI/ML enabled medical devices
Role of standards for medical devices

Regulators/Legislators

„consensus“ standards

Manufacturers

Health Delivery Organizations
Base „consensus“ standards for active medical devices *

Main objective derived from the legislation is to ensure that the benefit for end-users outweighs their residual risk in a traceable way.

ISO 13485 Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 14971 Medical devices — Application of risk management to medical devices
IEC 62304 Medical device software – Software life cycle processes
IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices

All standards for specific devices and device groups (several hundreds) in the area refer to the principles laid down in these base standard.

*active medical device: Supply of non-biological power is needed, includes software
Implications for AI Standards

All AI Standards for medical devices shall follow the established concepts for standards in this regulated area and use the principles laid down by the applicable legislation.

Terms, definitions and concepts shall be known and aligned with the legislation and the existing standards

The market access of the AI/ML enabled devices is jeopardized, if this alignment doesn’t happen
Proposed AI/ML standards architecture for MEE/MES

- IEC 82304-1
- IEC 60601-1
- IEC 61010-1
- ISO 14708-1
- IEC 14708-1
- IEC 61010-1
- IEC 60601-1
- IEC 82304-1

AI TC62/TC215 particular
AI TC62 particular
AI IVD particular
AI TC150/SC6

AI functional 3
AI functional 2
AI functional 1
AI functional 4

AI Base Standards (e.g. IEC 63450, ISO/IEC TS 4213)

- IEC 62304
- IEC 62366-1
- ISO 14971
- ISO 13485

Figure 1 in the 4th SNAIG Report (62/432/INF)
# Overview

## Existing standards sufficient; some additions for the application to AI-MD software different partners

<table>
<thead>
<tr>
<th>(all sorts of MD)</th>
<th>Clarification where additional factors are to be considered - basic standards are basically sufficient</th>
<th>Impact of patient as operator in the private space and cloud are hardly considered at present</th>
</tr>
</thead>
<tbody>
<tr>
<td>QMS, RMS, PMS, Security, Privacy</td>
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<table>
<thead>
<tr>
<th>Traditional ME (Hardware + non AI Software)</th>
<th>covered</th>
<th></th>
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<tbody>
<tr>
<td>SAMD</td>
<td>Extension/addition to 62304 for ML</td>
<td>clinical validation for SAMD</td>
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## New standards are necessary; IEC TC62 is in the lead or works in a JWG with partners

<table>
<thead>
<tr>
<th>(ML – MD, maybe AI - MD in general) Logic component</th>
<th>Quality metrics for external data component</th>
<th>clinical validation (data aspects, statistical effectiveness)</th>
<th>Techno-Vigilance necessary</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quality criteria and docu req. for „logic“ component</td>
<td>clinical validation (data aspects, statistical effectiveness)</td>
<td>clinical utility (effective benefit at the site)</td>
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<tr>
<td></td>
<td>Methods for building test sets</td>
<td>clinical validation (data aspects, statistical effectiveness)</td>
<td>Transparency in Usage and operation</td>
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<tr>
<th>(AI – MD) Bias (Ethics?)</th>
<th>Overarching process standard and consideration in all columns for symbolic AI + ML</th>
<th>clinical validation (data aspects, statistical effectiveness)</th>
<th>clinical validation (data aspects, statistical effectiveness)</th>
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## New standards are necessary; ISO TC215 is in the lead or works in JWG; IEC TC 62 contributes

<table>
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<tr>
<th>(ML – MD) Data component</th>
<th>Data Lifecycle process standard (incl. Selection, collection, vetting, documentation etc.)</th>
<th>Including changes based on PMS data or continuous learning</th>
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<td>Quality standards in design and development</td>
<td>clinical validation (data aspects, statistical effectiveness)</td>
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<td>Quality assurance methods and quality metrics</td>
<td>clinical validation (data aspects, statistical effectiveness)</td>
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<td>Methods for validation</td>
<td>clinical validation (data aspects, statistical effectiveness)</td>
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Thank you for listening

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