## Merged European CEN- and international ISO-standards for the validation of medical devices

<table>
<thead>
<tr>
<th>European standards</th>
<th>international ISO-standards (withdrawn and replaced)</th>
<th>New EN-ISO-standards (Combination of the existing EN- and ISO- standards)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EN 550 (replaced)</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Validation and routine monitoring for the sterilization in ethylene oxide sterilization processes | ISO 11135 Requirements for validation and routine monitoring for Ethylene Oxide sterilization processes | EN-ISO 11135-1 + 2
Requirements for the development, validation and routine monitoring of ethylene oxide sterilization processes for medical devices
1. Requirements
2. Guidance |
| **EN 552 (replaced)**  |
| Validation and routine monitoring for the sterilization in radiation sterilization processes | ISO 11137 Requirements for validation and routine monitoring for radiation sterilization processes | EN-ISO 11137-1 + 2 + 3
1. Requirements for validation and routine control for radiation sterilization processes
2. Selection of dose setting for products
3. Guidance |
| **EN 554 (replaced)**  |
| Validation and routine monitoring for the sterilization in steam sterilization processes | ISO/ DIS 13683 Requirements for validation and routine monitoring of moist heat sterilization processes in health care facilities | EN-ISO 17665-1 + 2
Requirements for the development, validation and routine monitoring of steam sterilization processes for medical devices in health care and industry
1. Requirements
2. Guidance |
| **EN 15424 (new, no ISO-Standard)**  |
| Validation of Low Temperature-Steam-Formaldehyde (LTSF) Processes | ISO 11134 Requirements for validation and routine monitoring of moist heat sterilization processes in industry | EN-ISO 14937
General requirements for the characterization of sterilization products and the development, validation and routine monitoring of sterilization processes |
| **EN 556 (remains)**  |
| Requirements on medical devices to be labeled "sterile“ (SAL ≤ 10⁶) | New EN ISO Standard for the validation of reprocessing sterile devices | EN-ISO 17664
Information to be provided by the manufacturer for the reprocessing of re-sterilizable medical devices |

04/2008