

# DIN EN ISO 23640:2013-09 (E)

## In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)

---

<b>Contents</b>		<b>Page</b>
<b>Foreword</b>	.....	<b>3</b>
<b>Introduction</b>	.....	<b>4</b>
<b>1</b>	<b>Scope</b> .....	<b>5</b>
<b>2</b>	<b>Normative references</b> .....	<b>5</b>
<b>3</b>	<b>Terms and definitions</b> .....	<b>5</b>
<b>4</b>	<b>General requirements</b> .....	<b>7</b>
<b>4.1</b>	<b>General principles</b> .....	<b>7</b>
<b>4.2</b>	<b>Protocol</b> .....	<b>8</b>
<b>4.3</b>	<b>Stability reports</b> .....	<b>8</b>
<b>5</b>	<b>Procedures</b> .....	<b>9</b>
<b>5.1</b>	<b>General</b> .....	<b>9</b>
<b>5.2</b>	<b>Real time stability evaluation</b> .....	<b>10</b>
<b>5.3</b>	<b>Accelerated stability evaluation</b> .....	<b>10</b>
<b>Bibliography</b>	.....	<b>11</b>
<b>Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC</b>	.....	<b>12</b>