

# DIN EN ISO 18113-1:2024-10 (E)

## **In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements (ISO 18113-1:2022)**

---

<b>Contents</b>	<b>Page</b>
<b>European foreword</b> .....	<b>3</b>
<b>Annex ZA</b> (informative) .....	<b>4</b>
<b>Foreword</b> .....	<b>7</b>
<b>Introduction</b> .....	<b>8</b>
<b>1 Scope</b> .....	<b>10</b>
<b>2 Normative references</b> .....	<b>10</b>
<b>3 Terms and definitions</b> .....	<b>10</b>
3.1 General terms and definitions for use with in vitro diagnostic medical devices .....	11
3.2 Performance characteristic terms and definitions.....	31
<b>4 General requirements for information supplied by the manufacturer</b> .....	<b>49</b>
4.1 General.....	49
4.2 Language.....	50
4.3 Symbols and identification colours.....	50
4.4 Values and nomenclature.....	50
4.5 Microbiological state.....	51
4.6 Instructions for use.....	51
4.7 Changes to the IVD medical device .....	52
4.8 Disclosure of residual risks.....	52
4.9 Identification of components.....	52
4.10 Assistance.....	52
<b>Annex A</b> (informative) <b>Performance characteristics of IVD medical devices</b> .....	<b>53</b>
<b>Bibliography</b> .....	<b>59</b>