Font size in the use of labeling of *in-vitro* diagnostics

There are no detailed guidelines about typography for labels of IVDs. Helpful sources for labeling of Medicinal Products (including the package leaflet) are available and applicable, such as the EC “Guideline on the readability of the labelling and package leaflet of medicinal products for human use” from 2009 [23].

Fonts should be easy to read, and distinguish between similar letters and numbers such as ‘l’ and “l” (capital “i”). For the IFU, a type size of 9 points, as measured in font ‘Times New Roman’, not narrowed, with a space between lines of at least 3 mm, should be considered as a minimum. For the labels of Medicinal Products, the same rules as for the IFU applies but characters of at least 7 points can be accepted (or of a size where the lower case “x” is at least 1.4mm in height). Font sizes are expressed in points, but the defined length of a point may vary. The definition of point used is the desktop publishing point (also called the PostScript point), which is defined as 1/72 of an inch or 0.3527 mm. Twelve DTP points make up a English pica. The unit of Cicero is similar to an English pica. There are about 1.063 picas to one Cicero; a pica is 4.233 mm and a Cicero is 4.5 mm. Due to the difference in font type and morphology, the font size is not easy to measure. The font size of the letter type can be best measured using a typometer and the Cicero scale (Rotring-werke Riepe KG, Hamburg, Germany) as the “kp” distance from the top of the highest ascender (top of the lower case letter k) to the bottom of the lowest descender (bottom of the lower case letter p).

Other considerations relate to **style and syntax**, such as the preference for an active style, use of headings and bullets (in preference not more than two levels of headings and six bullets in one list) and a column format. The widespread use of capitals and italics should be avoided (as they interfere with word-shape recognition). The paper of the IFU should be sufficiently thick (to minimize transparency) and uncoated (glossy paper reflects light and may hinder reading), and there should be enough contrast between text, figures and background. The readability level of a text (*i.e.* the skills needed to read it) can be expressed in different scales such as the Flesch-Kincaid scale. For patient educational materials, a Flesch-Kincaid scale ≤ 6 level is recommended [32,33].