

ANNEX I

ESSENTIAL REQUIREMENTS

B.DESIGN AND MANUFACTURING REQUIREMENTS

8. Information supplied by the manufacturer
- 8.3. In the case of devices containing or a preparation which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant danger symbols and labelling requirements of Directive 67/548/EEC⁽¹⁾ and Directive 88/379/EEC⁽²⁾ shall apply. Where there is insufficient space to put all the information on the device itself or on its label, the relevant danger symbols shall be put on the label and the other information required by those Directives shall be given in the instructions for use.

The provisions of the aforementioned Directives on the safety data sheet shall apply, unless all relevant information as appropriate is already made available by the instructions for use.

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

- (1) Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ([OJ L 196, 16.8.1967, p. 1](#)). Directive as last amended by Commission Directive 97/69/EC ([OJ L 343, 13.12.1997, p. 19](#)).
- (2) Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations ([OJ L 187, 16.7.1988, p. 14](#)). Directive as last amended by Commission Directive 96/65/EC ([OJ L 265, 18.10.1996, p. 15](#)).