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In vitro diagnostic medical devices
Requirements for vCJD assays

Information dated 22.2.2012

Please take note of the following changes and guidelines published by the European Commission:

- Commission directive 2011/100/EU of 20 December 2011 amending Directive 98/79/EC of the European Parliament and of the Council on in-vitro diagnostic medical devices (includes assays for variant Creutzfeldt-Jakob disease, vCJD, to Annex II List) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:341:0050:0051:EN:PDF

- Commission decision of 20 December 2011amending Decision 2002/364/EC on common technical specifications for in vitro diagnostic medical devices (concerns common technical specifications for vCJD blood screening assays). http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:341:0063:0064:EN:PDF

- MEDDEV 2.14/4 "CE marking of blood based in vitro diagnostic medical devices for vCJD based on detection of abnormal PrP" (http://ec.europa.eu/health/medical-devices/documents/guidelines/index_en.htm).

Therefore, the CE-marking of an assay for vCJD must involve the intervention of a recognised notified body for medical devices.

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