

Required Elements for a Declaration of Conformity to a Recognized Standard

Required Element	Present	Inadequate or Missing
a. An identification of the applicable recognized consensus standards that were met.		
b. A statement, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below.		
c. An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review (e.g. An identification of an alternative series of tests that were performed).		
d. An identification, for each consensus standard, of any requirements that were not applicable to the device.		
e. A specification of any deviations from each applicable standard that were applied.		
f. A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference.		
g. The name and address of the testing laboratory and/or certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations.		

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