Note to be linked to SG1 document on the *Principles of In Vitro Diagnostic (IVD) Medical Devices Classification* (SG1/N045) when it is published on the GHTF website as a "Proposed Document".

REQUESTS FOR COMMENTS ON SG1/N045 of 31 OCTOBER 2006: *Principles of In Vitro Diagnostic (IVD) Medical Devices Classification*

This document is published after extensive discussion within the Study Group. Before proceeding to a Final Document, SG1 seeks comments on all aspects of its contents. In particular, we would like to drawn your attention to Rule 4 (Page 13) which classifies devices as Class C devices if they are intended for either near-patient testing or self testing.

26 February 2003