SCHEDULE 1

Amendment of the Medical Devices Regulations 2002

Insertion of regulation 36A

13. After regulation 36 (CE marking of *in vitro* diagnostic medical devices) insert—

"**UK(NI) indication: in vitro diagnostic medical devices**

36A.—(1) Where the CE marking referred to in regulation 36 is affixed on the basis of an assessment or a certificate issued by a notified body established in the United Kingdom, a UK(NI) indication must be affixed in relation to the device, in accordance with this regulation.

(2) The UK(NI) indication must be affixed—

(a) visibly, legibly and indelibly; and

(b) before a relevant medical device is placed on the market in Northern Ireland.

(3) The UK(NI) indication must accompany the CE marking, wherever that is affixed in accordance with regulation 36.

(4) The UK(NI) indication must be affixed by the manufacturer.

(5) Anyone who places a medical device on the market in Northern Ireland must ensure that the manufacturer has complied with their obligations under this regulation.

(6) No person shall supply a relevant device unless the manufacturer has affixed a UK(NI) indication as required by this regulation, if that supply is also a placing on the market or putting into service, or that supply is of a device that has been placed on the market or put into service".".