SCHEDULE 2

Amendments to EU tertiary legislation

PART 3

Amendments to Commission Regulation (EU) No 722/2012

10. In Article 3 (which relates to risk analysis and risk management), for paragraph 1, substitute—

"**1.** Before lodging an application for a conformity assessment for the purpose of complying with regulation 13 or regulation 27 of the Medical Devices Regulations 2002, the manufacturer of medical devices referred to in Article 1(1) of this Regulation or their UK responsible person must carry out the risk analysis and risk management scheme set out in Annex I to this Regulation.".