SCHEDULE

Amendment of the 2016 Regulations

Substitution of regulation 12 of the 2016 Regulations (grant of EU conformity approval: obligations of a notified body)

10. For regulation 12 of the 2016 Regulations (grant of EU conformity approval: obligations of a notified body) substitute—

"**Grant of United Kingdom conformity approval: obligations of an approved body**

12.—(1) An approved body must—

(a) decide whether to grant or refuse United Kingdom conformity approval in accordance with the provisions of Schedule 2; and

(b) where an application is made under Part 1 of Schedule 2 (Module B), produce an evaluation report recording the activities undertaken in accordance with paragraph 5 of that Schedule and their outcomes.

(2) Where an approved body grants United Kingdom conformity approval, it must—

(a) for the type approval of equipment under Part 1 (Module B) of Schedule 2, issue a certificate containing the information specified in paragraph 7 of that module;

(b) for approval of a quality system under Part 2 (Module D) or Part 3 (Module E) of Schedule 2, notify the manufacturer of its decision in writing, including the conclusions of the audit of the quality system and the reasons for its decision; or

(c) where verifying a product under Part 4 (Module F) or Part 5 (Module) G of Schedule 2, issue a certificate of conformity for that product.

(3) Where an approved body refuses United Kingdom conformity approval, it must notify the manufacturer, giving detailed reasons for its decision.

(4) An approved body must—

(a) periodically audit a quality system that it has approved; and

(b) provide the manufacturer with a report containing the results of the audit.

(5) Where an approved body knows or has reason to believe that—

(a) equipment to which it has granted United Kingdom conformity approval no longer complies with applicable international standards; or

(b) a manufacturer has failed to comply with an obligation under regulation 20(1) to (6) (obligations of a manufacturer),

it must require the manufacturer to take immediate corrective measures to ensure that the equipment complies with applicable international standards, and where necessary, suspend or withdraw its approval for that equipment.

(6) Following the grant of United Kingdom conformity approval, an approved body must comply with the provision of information requirements in Schedule 2 and must, in particular, inform the Secretary of State about any refusal, restriction, suspension or withdrawal of a conformity certificate and, on request, information about the conformity assessment activities performed within the scope of that approved body's designation, and any other activity performed.".