

SCHEDULE 1

Amendment of the Medical Devices Regulations 2002

Insertion of regulation 19B

7. After regulation 19 insert—

“Requirement to appoint a UK responsible person for general medical devices

19B.—(1) Paragraph (2) applies in relation to a manufacturer who—

- (a) does not have a registered place of business in the United Kingdom;
- (b) has not designated an authorised representative who has a registered place of business in Northern Ireland; and
- (c) places a relevant device, other than a Class I or custom-made device, on the market in Northern Ireland.

(2) A manufacturer to whom this paragraph applies must appoint a person with a registered place of business in the United Kingdom as their UK responsible person to carry out the tasks described in regulations 19(2) and (5).”.