STATUTORY INSTRUMENTS

2010 No. 557

FEES AND CHARGES

The Medical Devices (Fees Amendment) Regulations 2010

Made - - - -	*25th February 2010*
Laid before Parliament	*4th March 2010*
Coming into force - -	*1st April 2010*

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(**a**) and section 56(1) and (2) of the Finance Act 1973(**b**).

The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972(**c**) in relation to medical devices.

The Treasury has consented to the making of these Regulations as required by section 56(1) of the Finance Act 1973.

Citation and commencement

1. These Regulations may be cited as the Medical Devices (Fees Amendment) Regulations 2010 and shall come into force on 1st April 2010.

Amendment of the Medical Devices (Consultation Requirements) (Fees) Regulations 1995

2.—(1) The Medical Devices (Consultation Requirements) (Fees) Regulations 1995(**d**) are amended as follows.

(2) In regulation 3 (fees)—

(a) in paragraph (1)—

(i) in sub-paragraph (a), for "£4,549" substitute "£4,595"; and

(ii) in sub-paragraph (b), for "£10,605" substitute "£10,711";

(b) in paragraph (2)—

(i) in sub-paragraph (a), for "£900" substitute "£909"; and

(ii) in sub-paragraph (b), for "£2,517" substitute "£2,542";

(**a**) 1972 c.68. Under section 57(1) of the Scotland Act 1998 (c.46), despite the transfer to Scottish Ministers of functions in relation to implementing obligations under European Union law in relation to devolved matters, the functions of the Secretary of State in relation to implementing these obligations continues to be exercisable by the Secretary of State as regards Scotland.

(**b**) 1973 c.51.

(**c**) The Secretary of State was designated in relation to measures relating to active implantable medical devices in S.I. 1991/2289 and in relation to measures relating to medical devices other than active implantable medical devices in S.I. 1993/2661.

(**d**) S.I. 1995/449; relevant amending instruments are S.I. 2007/803, 2008/530 and 2009/383.

(c) in paragraph (3)—

(i) in sub-paragraph (a), for "£4,549" substitute "£4,595"; and

(ii) in sub-paragraph (b), for "£10,605" substitute "£10,711";

(d) in paragraph (4)—

(i) in sub-paragraph (a), for "£900" substitute "£909"; and

(ii) in sub-paragraph (b), for "£2,517" substitute "£2,542"; and

(e) in paragraph (5)—

(i) in sub-paragraph (a), for "£46,531" substitute "£46,996"; and

(ii) in sub-paragraph (b), for "£11,552" substitute "£11,668".

(3) In paragraph (2) of regulation 3A (fees for pre-consultation meetings)—

(a) in sub-paragraph (a), for "£824" substitute "£832";

(b) in sub-paragraph (b), for "£1,044" substitute "£1,054";

(c) in sub-paragraph (c), for "£1,428" substitute "£1,443"; and

(d) in sub-paragraph (d), for "£1,813" substitute "£1,831".

Amendment of the Medical Devices Regulations 2002

3.—(1) The Medical Devices Regulations 2002(**a**) are amended as follows.

(2) In regulation 54 (fees payable in connection with the designation etc of notified bodies)—

(a) in paragraph (1)—

(i) in sub-paragraph (a), for "£930" substitute "£960"; and

(ii) in sub-paragraph (b), for "£3,700" substitute "£3,840";

(b) in paragraph (2), for "£1,810" substitute "£1,880";

(c) in paragraph (3)—

(i) in sub-paragraph (a), for "£4,500" substitute "£4,670";

(ii) in sub-paragraph (b)(i), for "£7,400" substitute "£7,670";

(iii) in sub-paragraph (b)(ii), for "£5,550" substitute "£5,760";

(iv) in sub-paragraph (b)(iii), for "£3,700" substitute "£3,840"; and

(v) in sub-paragraph (c), for "£3,700" substitute "£3,840"; and

(d) in paragraph (3A)—

(i) in sub-paragraph (a)(i), for "£261" substitute "£271"; and

(ii) in sub-paragraph (a)(ii), for "£72.56" substitute "£75.24".

(3) In regulation 55 (fees payable in connection with the designation etc of conformity assessment bodies)—

(a) in paragraph (1)—

(i) in sub-paragraph (a), for "£930" substitute "£960"; and

(ii) in sub-paragraph (b), for "£3,700" substitute "£3,840";

(b) in paragraph (2), for "£1,810" substitute "£1,880";

(c) in paragraph (3)—

(i) in sub-paragraph (a), for "£4,500" substitute "£4,670";

(ii) in sub-paragraph (b), for "£3,700" substitute "£3,840";

(iii) in sub-paragraph (c), for "£1,810" substitute "£1,880"; and

(iv) in sub-paragraph (d), for "£3,700" substitute "£3,840";

(**a**) S.I. 2002/618; relevant amendments have been made by S.I. 2003/1697, 2007/803, 2008/530 and 2009/383.

(d) in paragraph (3A), for "£4,500" substitute "£4,670" and for "£1,810" substitute "£1,880";

(e) in paragraph (3B), for "£3,700" substitute "£3,840" and for "£1,810" substitute "£1,880";

(f) in paragraph (3C), for "£1,810" substitute "£1,880"; and

(g) in paragraph (3D)—

(i) in sub-paragraph (a)(i), for "£261" substitute "£271"; and

(ii) in sub-paragraph (a)(ii), for "£72.56" substitute "£75.24".

Signed by authority of the Secretary of State for Health

Mike O'Brien
Minister of State,
Department of Health

22nd February 2010

We consent

Tony Cunningham
Steve McCabe
Two of the Lords Commissioners of Her Majesty's Treasury

25th February 2010

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make amendments to the Medical Devices (Consultation Requirements) (Fees) Regulations 1995 ("the 1995 Regulations") and the Medical Devices Regulations 2002 ("the 2002 Regulations").

The 1995 Regulations prescribe the fees which are payable where a notified body consults the competent body in accordance with Council Directive 93/42/EEC concerning medical devices(**a**). Regulation 2 of these Regulations amends the 1995 Regulations by increasing the amounts of the fees specified in regulations 3 and 3A of those Regulations (overall average increase of 1%).

The 2002 Regulations contain the legislative measures necessary for the implementation of the European Union scheme for regulating the placing on the market and putting into service of medical devices, set out in Council Directive 90/385/EEC on the approximation of the laws of Member States relating to active implantable medical devices(**b**), Council Directive 93/42/EEC concerning medical devices and Council Directive 98/79/EC on *in vitro* diagnostic devices(**c**). Regulation 3 of these Regulations amends regulations 54 and 55 of the 2002 Regulations, which provide for the fees payable in connection with the designation etc of UK notified bodies and EU conformity assessment bodies. The overall increase in fees to the medical devices sector is 1%, as all other fees remain unchanged.

(**a**) OJ No. L169, 12.7.93, p.1 to which amendments have been made by Directive 98/79/EC of the European Parliament and of the Council (OJ No. L 331, 7.12.1998, p.1), Directive 2000/70/EC of the European Parliament and of the Council (OJ No. L313, 13.12.2000, p.22), Directive 2001/104/EC of the European Parliament and of the Council (OJ No. L6, 10.1.2002, p.50), Regulation (EC) No. 1882/2003 of the European Parliament and of the Council (OJ No. L284, 31.10.2003, p.1) and Directive 2007/47/EC of the European Parliament and of the Council (OJ No. L247, 21.9.2007, p.21).

(**b**) OJ No. L189, 20.7.90, p.17 to which amendments have been made by Council Directive 93/42/EEC, Council Directive 93/68/EEC (OJ No. L220, 30.8.1993, p.1), Regulation (EC) No. 1882/2003 and Directive 2007/47/EC.

(**c**) OJ No. L331, 7.12.98, p.1 to which amendments have been made by Regulation (EC) No. 1882/2003.

An impact assessment of the effect that this instrument will have on the costs of business is available from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ and copies have been placed in the libraries of both Houses of Parliament.

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