
STATUTORY INSTRUMENTS

1994 No. 3119

MEDICINES

**The Medical Devices (Consequential
Amendments—Medicines) Regulations 1994**

<i>Made</i>	- - - -	<i>7th December 1994</i>
<i>Laid before Parliament</i>		<i>8th December 1994</i>
<i>Coming into force</i>	- -	<i>1st January 1995</i>

The Secretary of State and the Minister of Agriculture, Fisheries and Food, acting jointly, in exercise of the powers conferred by section 2(2) of the European Communities Act 1972⁽¹⁾ and of all other powers so enabling them, hereby make the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Medical Devices (Consequential Amendments—Medicines) Regulations 1994 and shall come into force on 1st January 1995.

Amendment of the Medicines Act 1968

2. In section 130 of the Medicines Act 1968⁽²⁾ (meaning of “medicinal product” and related expressions)—

- (a) in subsection 5(b) for the words “where the medication has a curative function which is not limited to sterilising the dressing” there shall be substituted the words “within subsection (5A) below”;
- (b) after subsection (5) the following subsection shall be inserted—
 - “(5A) Medicated dressings are within this subsection (and accordingly are not excluded from the definition of “medicinal product” by subsection (5)(b) above) if—
 - (a) their medication has a curative function which is not limited to sterilising the dressing; and
 - (b) they are not dressings of a kind to which the requirements of Article 2 of Council Directive 93/42/EEC⁽³⁾ (placing medical devices on the market and putting

(1) 1972 c. 68; the Secretary of State and the Minister of Agriculture, Fisheries and Food have been designated for the purposes of section 2(2) in relation to medicinal products by S.I.1972/1811; the Secretary of State has also been designated for those purposes in relation to measures relating to medical devices other than active implantable medical devices by S.I. 1993/2661.
(2) 1968 c. 67.
(3) O.J. No. L 169 12.7.93 p.1.

them into service) apply or would apply but for Article 4 (devices intended for special purposes) or 22 (transitional provisions) of that Directive.”.

Amendment of the Medicines (Surgical Materials) Order 1971

3. In the Medicines (Surgical Materials) Order 1971(4)—
- (a) in Article 3 (application of specified provisions of the Act to certain surgical materials) after the words “it is hereby directed that” there shall be added the words “, subject to Article 4 of this Order.”; and
 - (b) after Article 3 the following Article shall be inserted—

“Exception

4. No provision of the Act shall have effect under Article 3 of this Order in relation to an article or substance of a kind to which the requirements of Article 2 of Council Directive [93/42/EEC\(3\)](#) (placing medical devices on the market and putting them into service) apply or would apply but for Article 4 (devices intended for special purposes) or 22 (transitional provisions) of that Directive.”.

Amendment of the Medicines (Dental Filling Substances) Order 1975

4. In the Medicines (Dental Filling Substances) Order 1975(5)—
- (a) in paragraph (1) of Article 2 (application of specified provisions of the Act to dental filling substances) after the words “it is hereby directed that, subject” there shall be added the words “to Article 3 of this Order and”; and
 - (b) after Article 2 the following Article shall be inserted—

“Exception

3. No provision of the Act shall have effect under Article 2 of this Order in relation to an article or substance of a kind to which the requirements of Article 2 of Council Directive [93/42/EEC\(3\)](#) (placing medical devices on the market and putting them into service) apply or would apply but for Article 4 (devices intended for special purposes) or 22 (transitional provisions) of that Directive.”.

Amendment of the Medicines (Specified Articles and Substances) Order 1976

5. In the Medicines (Specified Articles and Substances) Order 1976(6)—
- (a) in Article 2 (application of specified provisions of the Act to articles and substances described in Schedule 1) after the words “it is hereby directed that, subject” there shall be added the words “to Article 3 of this Order and”; and
 - (b) after Article 2 the following Article shall be inserted—

“Exception

3. No provision of the Act shall have effect under Article 2 of this Order in relation to an article or substance of a kind to which the requirements of Article 2 of Council Directive

(4) S.I. [1971/1267](#).

(3) O.J. No. L 169 12.7.93 p.1.

(5) S.I. [1975/533](#).

(3) O.J. No. L 169 12.7.93 p.1.

(6) S.I. [1976/968](#).

[93/42/EEC\(3\)](#) (placing medical devices on the market and putting them into service) apply or would apply but for Article 4 (devices intended for special purposes) or 22 (transitional provisions) of that Directive.”.

7th December 1994

Virginia Bottomley
One of Her Majesty’s Principal Secretaries of
State,
Department of Health

7th December 1994

Angela Browning
Parliamentary Secretary, Ministry of Agriculture,
Fisheries and Food

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines Act 1968 (“the Act”) and Orders under it in consequence of the implementation of Council Directive 93/42/EEC concerning medical devices (O.J. No. L169 12.7.93 p.1) by the [Medical Devices Regulations 1994 \(S.I. No. 3017\)](#).

Regulation 2 amends the definition of “medicinal product” in section 130 of the Act so that it does not include certain medicated dressings.

Regulation 3 amends the Medicines (Surgical Materials) Order 1971 so that it ceases to apply provisions of the Act to certain surgical ligatures, surgical sutures and absorbent or protective materials.

Regulation 4 amends the Medicines (Dental Filling Substances) Order 1975 so that provisions of the Act cannot be applied to dental filling substances by appointing an additional appointed day. No such day has been appointed for the purposes of that Order and so the Act has not been applied to substances used for filling dental cavities.

Regulation 5 amends the Medicines (Specified Articles and Substances) Order 1976 so that it ceases to apply provisions of the Act to certain intra-uterine contraceptive devices and to substances associated with contact lenses. Regulation 5 also amends that Order so that provisions of the Act cannot be applied to contact lenses from an additional appointed day. No additional appointed day has been appointed for the purpose of applying provisions of the Act to contact lenses.