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STATUTORY INSTRUMENTS

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**2005 No. 2909**

**CONSUMER PROTECTION**

**The Medical Devices (Amendment) Regulations 2005**

<i>Made</i>	- - - -	<i>18th October 2005</i>
<i>Laid before Parliament</i>		<i>25th October 2005</i>
		<i>22nd November</i>
<i>Coming into force</i>	- -	<i>2005</i>

The Secretary of State, being a Minister designated for the purposes of section 2(2) of the European Communities Act 1972<sup>(1)</sup> in relation to measures relating to medical devices<sup>(2)</sup>, in exercise of the powers conferred by the said section 2(2), and in exercise of the powers conferred by section 27(2) of the Consumer Protection Act 1987<sup>(3)</sup>, makes the following Regulations:

**Citation and commencement**

1. These Regulations may be cited as the Medical Devices (Amendment) Regulations 2005 and shall come into force on 22nd November 2005.

**Amendment of regulation 61 of the Medical Devices Regulations 2002**

2. In regulation 61 of the Medical Devices Regulations 2002 (enforcement etc.)<sup>(4)</sup>—
- (a) in paragraph (3), omit “for the purposes of Part II of the 1987 Act”; and
  - (b) after paragraph (7), insert the following paragraph—

“(7A) In paragraph (3), “consumer goods” means any goods which are ordinarily intended for private use or consumption.”

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(1) 1972 c. 68.  
(2) 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.  
(3) 1987 c. 43.  
(4) S.I. 2002/618; there are no relevant amending instruments.

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**Status:** *This is the original version (as it was originally made). UK  
Statutory Instruments are not carried in their revised form on this site.*

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Signed by authority of the Secretary of State for Health

18th October 2005

*Jane Kennedy*  
Minister of Health,  
Department of Health

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations further amend the Medical Devices Regulations 2002 (“the principal Regulations”), which contain the legislative measures necessary for the implementation of the European Community scheme for regulating the placing on the market and the putting into service of medical devices.

Regulation 2 amends regulation 61 of the principal Regulations, which makes provision for enforcement. Paragraph (3) of that regulation had the effect that local authorities had a duty to enforce the Regulations in so far as they related to “consumer goods”, as defined in section 10(7) of Part II of the Consumer Protection Act 1987. Section 10 has been repealed by the General Product Safety Regulations 2005 ([SI 2005/1803](#)). Regulation 2(a) removes the reference to Part II of the 1987 Act. Regulation 2(b) inserts regulation 61(7A), defining the term “consumer goods”, so that local authorities continue to have an obligation to enforce in relation to goods ordinarily intended for use by consumers.

A full regulatory impact assessment has not been produced for this instrument as it has no impact on the costs of business.