STATUTORY INSTRUMENTS

2003 No. 1697

The Medical Devices (Amendment) Regulations 2003

Amendment of regulation 17 of the principal Regulations

7. In regulation 17 of the principal Regulations (manufacturers etc. and conformity assessment procedures for general medical devices), after paragraph (3) there is added the following paragraphs—

"(4) Subject to paragraph (5), where a relevant device is manufactured utilising either animal tissue which is rendered non-viable or non-viable products derived from animal tissue, the manufacturer of that device or, where applicable, his authorised representative who is required to carry out, or carries out or has carried out the risk analysis and risk management procedures set out in the Annex to Directive 2003/32 shall observe the manufacturer's obligations set out in those procedures.

(5) Paragraph (4) shall not apply to a relevant device which is not intended to come into contact with the human body or which is intended to come into contact with intact skin only.".

Status:
Point in time view as at 01/04/2004. This version of this provision has been superseded.

Changes to legislation:
There are currently no known outstanding effects for the The Medical Devices (Amendment) Regulations 2003, Section 7.