
STATUTORY INSTRUMENTS

2003 No. 1697

The Medical Devices (Amendment) Regulations 2003

Amendment of regulation 47 of the principal Regulations

14. In regulation 47 of the principal Regulations (general matters relating to UK notified bodies), after paragraph (8) there is added the following paragraphs—

“(9) Subject to paragraph (10), a UK notified body that is designated to carry out the tasks referred to in article 5 of Directive 2003/32 shall, when performing conformity evaluation of a relevant device manufactured utilising either animal tissue which is rendered non-viable or non-viable products derived from animal tissue, evaluate the matters mentioned in article 5.2 of Directive 2003/32, and in so doing shall—

- (a) take account of any relevant certificate of suitability that has been issued by the European Directorate for the Quality of Medicines in respect of either any animal tissues which are rendered non-viable or non-viable products derived from animal tissue which are utilised or intended to be utilised in that device; or
- (b) if no relevant certificate of suitability is available—
 - (i) seek the opinion of the Secretary of State and through the Secretary of State the opinion of other Member States on the UK notified body’s evaluation and conclusions on the risk analysis and risk management of the animal tissues or products derived from animal tissue utilised or intended to be utilised in that device, as established by the manufacturer or his authorised representative, and
 - (ii) where the UK notified body receives any comments from the Secretary of State and where applicable from other Member States that have commented within twelve weeks of those opinions being sought by the Secretary of State, give due consideration to any such comments,

and where the Secretary of State’s opinion is sought pursuant to sub-paragraph (b)

(i), the UK notified body shall supply him with the information and documents he needs or reasonably requests in order to formulate his opinion.

(10) Paragraph (9) 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.”.