Summary Evaluation Report
on the Assessment of a Medical Device by the Notified Body
for Conformity with Council Directive 93/42/EEC and Commission Directive 2003/32/EC.

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Reporter Reference

1. Report sent by :	**2. Notified Body No :**	**3. Country :**
4. Sent by:	**5. Contact person:**	**6. Telephone:**
7. Fax:	**8. E-mail:**	**9. Client Reference :**

10. Our Designating Competent Authority has confirmed the scope of our activities meets the provisions of Article 16 of Council Directive 93/42/EEC and Article 4 of Commission Directive 2003/32/EC.

Medical Device Data

11. Product description and composition:
12. Information on intended use:
13. Nature of the starting tissue(s), animal species(s) and geographical source(s):
14. A description of the key elements adopted to minimise the risk of infection:
15. An estimate of the TSE risk arising from the use of the product, taking into account the likelihood of contamination of the product, the nature and duration of patient exposure:
16. A justification for the use of animal tissues or derivatives in the medical device, including a rationale for the acceptability of the overall TSE risk estimate, the evaluation of alternative materials and the expected clinical benefit:
17. The approach to the auditing of source establishments and/or third party suppliers for the animal material used by the device manufacturer:

Notified Body Statement

18. Conclusion of this assessment: Based on the evaluation of data and the assessment process it is our <u>preliminary decision</u> this application meets the requirements of conformity with Council Directive 93/42/EEC and Commission Directive 2003/32/EC.

Distribution Record

19. This report was sent on .....2004 to the Coordinating Competent Authority of .....to seek an opinion from the Competent Authorities of the other Member States.