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COMMERCIAL IN CONFIDENCE

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COMMITTEE ON DENTAL AND SURGICAL MATERIALS

WORKING PARTY ON BOVINE SPONGIFORM ENCEPHALOPATHY

PAPER

UPDATE ON SURGICAL CATGUT

1. Introduction

This is a brief update on the current status of Catgut Sutures

2. Background

- 2.1 At its second meeting on 10 January 1990 the Working Party on Bovine Spongiform Encephalopathy reviewed progress towards changing from UK raw material to bovine small intestine sourced from Australia and New Zealand.

Detailed consideration was given to the Company's proposed strategy for decontamination of the manufacturing facilities prior to the changeover (Appendix 1 ).

- 2.2 As recommended by the Working <sup>Party</sup> Group, details of stocks held and product supplied were kept under review, particularly in the light of the Commission Decision 90/200/EEC of 9 April 1990 regarding export from UK of bovine tissues and organs for uses other than human consumption.

3. Progress

- 3.1 In a Position Paper of 16 January 1990 the company gave projected dates for the decontamination operation, and a timescale for changeover of supplied finished sutures to 100% Australian sourced product (Appendix 2).
- 3.2 The factory clean down was in fact completed slightly ahead of the projected schedule (Appendix 3).
- 3.3 Manufacture of raw strings from Australian raw material commenced on 31 January 1990. Manufacture of finished product from Australian material commenced 16 March approximately.

- 3.4 On 4 May 1990 the product licence was varied to state source of sheep submucosa and beef serosa used by Ltd as only Australia and New Zealand (no source having previously been stated).
- 3.5 Following EC Commission Decision 90/200/EEC, on 16 May the Company gave an undertaking that all consignments of sterilised surgical catgut supplied to Member states would comprise exclusively product manufactured from Australian and New Zealand raw material.
- 3.6 The Company has confirmed that by 30 June 1990, 100% of sterilised surgical catgut products supplied to the UK market would be manufactured from raw material of Australian and New Zealand origin (Appendix 4).

4. Secretariat Comment

The Company has implemented as rapidly as possible the changeover from UK sourced raw material. 100% finished product supplied is now derived from material sourced from Australia and New Zealand.

The advice of the Working Party is sought on the Secretariat view that no further action is necessary on the part of the Licensing Authority.

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