Kiwimed Ltd. Lynton House 7-12 Tavistock Square London, WC1H 9LT United Kingdom

Ms. C Fuller, Technology Appraisals Manager, National Institute for Clinical Excellence, MidCity Place, 71 High Holborn, London WC1V 6NA.

10th January, 2006.

Dear Ms. Fuller,

<u>Kiwimed Response to Assessment Report: Coronary Artery Stents for the Treatment of</u> <u>Ischaemic Heart Disease (Update to Guidance No. 71).</u>

There are a few things that we wish to draw your attention to in regard to Kiwimed's participation in the above assessment.

- 1. Through out the report the name Kiwimed has been written in different ways. It should read: Kiwimed Ltd.
- 2. At the time that we submitted our dossier the ISAR TEST study was not published. It is now peer reviewed and was presented during the TCT congress in October. It has also now been published in the Circulation Journal (Jan 06) as per the attached copy. We request that your assessment report now acknowledges this and the tables such as 4.1 reflect this progress.
- 3. In the economic submission appraisal (Table 7-4) there has been a miscalculation of Kiwimed's price premium. Our price differential should read £170 which is under that suggested as the threshold for use of DES as opposed to BMS (section 10.3)
- 4. Section 8.4.3 should make some mention to non Polymer based systems such as our own as there is now considerable evidence to suggest that anti-platelet therapy could be reduced to BMS levels where a non polymeric stent is used and that risk of late thrombosis and additional cost or MACE is reduced.
- 5. Appendix table 8 has not shown the ISAR Project 1 Yukon DES late loss data and only BMS late loss data has been shown. The Yukon DES should read late loss of 0.46mm (in Stent) and 0.36 (in Segment).

I trust that these suggested amendments meet with your approval

Regards

Managing Director