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ENDORSEMENT OF NAVIGATION MANUALS POLICY

As of 3 February 2010, it is our company policy that we shall review Navigation Manuals as we become aware of them. We will evaluate the Navigation Manuals and they will either be “endorsed,” “not endorsed,” or “marked for feedback” to the author and/or publisher. If inappropriate verbiage is used by an author and/or publisher, this office will attempt to correct any such problems through any communication lines which are open. If unsatisfactory results are met, this office may chose to have a legal advisory team take greater action. Our decision will be based on appropriateness of information and compliance to the Indications for Use and any other regulatory requirements.

Furthermore, from Revision I of SCIO User Manual 200003 we suggest that a Navigation Manual which is endorsed by Maitreya Kft. should be used. In the SCIO User Manual from Revision I you can find which Navigation Manuals are endorsed. Regarding any unendorsed Navigation Manual please be cautious of any suggestions of off-label use.

If you have any questions on this policy, please contact Richard Lloyd, Regulatory Manager on richard@qxsubspace.com.