Proxy AP Validation Certificate

The Proxy Automatic Endoscope Reprocessing (AER) Chemistry System has been developed for use in Soluscope AERs using a two part Peracetic Acid based high level disinfectant/sterilant system. The entire Proxy product range has been validated for use in Soluscope AERs and are direct equivalents to their Soluscope counterparts.

Proxy AP (ARTG Entry 274095) complies with relevant therapeutic goods legislation including the requirements outlined in the Australian Regulatory Guidelines for Medical Devices and Therapeutic Goods Order No. 54 – Standard for composition, packaging, labelling and performance of disinfectants and sterilants (TGO54). The Therapeutic Goods Administration reviewed the regulatory file for Proxy AP during the June 2016 surveillance audit of Whiteley Corporation.

ISO 15883.4, section 6.12.1, states that "National regulatory requirements can specify approval procedures for disinfectants to be used in WDs for medical devices. Compliance with these national requirements shall be deemed to meet the requirements within the territory where these requirements apply". Proxy AP has undergone a wide array of validation testing in accordance with the statutory performance standards given in TGO54.

Table 1 shows the equivalence between Proxy AP and Soluscope AP.

Test Critieria	Proxy P versus Soluscope P	Proxy A versus Soluscope A	Proxy P+A versus Soluscope P+A
Registered on ARTG	✓	✓	✓
TG054 Compliant	✓	✓	✓
Materials Compatibility	✓	✓	✓
Microbial Efficacy	✓	✓	✓
Appearance	✓	✓	✓
Odour	✓	✓	✓
Refractive Index	✓	✓	✓
Specific Gravity	✓	✓	✓
Hydrogen Peroxide	✓	N/A	✓
Peracetic Acid	✓	N/A	✓
Benzotriazole	N/A	✓	✓
pH	✓	✓	✓

Note: ✓ = Testing confirms direct equivalence

Table 1 – Equivalence of Proxy AP and Soluscope AP

The products provided by Soluscope are not unique or patentable. Proxy products provide the direct equivalent of their Soluscope counterparts, as discussed above, and comply to the relevant sections of ISO 15883 and the Australian regulatory system for medical devices.

Whiteley Medical certifies that the Proxy Chemistry Range has been validated for use in the Soluscope AERs, using a two part Peracetic Acid based high level disinfectant/sterilant system, and that when the AER is functioning as per the manufacturer's regulatory requirements, the Proxy Chemistry Range will be substantially equivalent for the same Endoscope Type Testing conducted by Soluscope.

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