DECLARATION OF CONFORMITY

This Declaration of Conformity was prepared in accordance with Annex V of the Medical Device Directive 93/42/EEC.

Synapse Electroceutical Ltd declare that the Class IIa medical device stated below complies with the Medical Device Directive 93/42/EEC incorporating Directive 2007/47/EC and all harmonised standards transposed into UK law in SI 618, the Medical Device Regulation.

Conformity Assessment was carried out by SGS United Kingdom Ltd who audited the quality assurance system in accordance with the Medical Device Directive 93/42/EEC: 1993 Annex II (excluding section 4) and ISO 13485:2016.

Synapse Electroceutical Ltd are entitled to use the CE0120 Marking.

Accel-Heal®: non sterile single use microcurrent stimulation device for improved rate of wound healing.

Signed:

Andrew Wildman
CFO

Date: 18/09/18

On behalf of:
Synapse Electroceutical Ltd
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