

CERTIFICATE OF TEST

Perry Baromedical Corporation

3750 Prospect Avenue,
Riviera Beach, FL 33404 USA

Product Name: Sigma and Sigma Elite

Model(s): Sigma Elite 34, Sigma Elite 36, Sigma Elite 40,
Sigma 34, Sigma 36, Sigma 40,
Sigma ICON 30


Report No(s): F2P21869D-03S-R2, F2P21869D-01S

The above-listed product(s) were tested and found to comply with the following standard(s):*

Standard: IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 (or IEC 60601-1:2012 reprint)- Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance

Standard: IEC 60601-1-6:2010, AMD1:2013, AMD2:2020- Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability




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Safety Technical Manager
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**This Certificate is based on the evaluation of a representative sample(s) of the above-mentioned product(s) on a voluntary basis. This is to confirm that the tested sample(s) were tested to all or part of the standard(s) listed herein, as detailed in the applicable test report(s). It does not imply the assessment of the production of the product or approval of the manufacturing process or facility. The holder is authorized to use the Certificate to provide evidence of conformity as detailed above with the authority of F2 Labs.*

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