



**PRESTAN®**

# **Declaration of Conformity**

## ***Quality Systems and Regulatory Compliance***

***Prestan 2019***

*Prestan is a developer and manufacturer of emergency medical training products. We employ a comprehensive set of processes and methods to insure that our products are safe, reliable and effective. Our quality systems require that our internal processes as well as those of our suppliers and contract manufacturers include statistically based inspection plans and audits to insure product consistency, compliance and control of non-conforming goods.*

*We certify that our products conform to all mandatory industry regulations and as well as a number of additional standards on a voluntary basis. The following listing identifies those standards which are adhered to subject to the standard's relevancy to each product, process and resource utilized.*

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|----------------------------------|---|
| ○ <i>FDA GMP, Class I</i>        | <i>FDA's Good Manufacturing Practices: Quality System Requirements</i>  |
| ○ <i>ANSI/ASQC Z1.4</i>          | <i>Statistical Sampling Procedures and Tables for Inspection of Materials and Finished Goods</i>                        |
| ○ <i>RoHS (2015/863/EU)</i>      | <i>Restriction of Hazardous Substances in Electronic Products and Components</i>  |
| ○ <i>EU 2005/84/EC</i>           | <i>Restriction of Hazardous Substances: Phthalates in PVC based plastics</i>  |
| ○ <i>Toxics In Packaging Act</i> | <i>(and EU 94/62/EC) Restriction of Hazardous Substances in Packaging</i>   |
| ○ <i>UL94HB</i>                  | <i>Flammability Standard for Plastic Resins</i>   |
| ○ <i>EN 61326 / IEC 61326</i>    | <i>Electro-Magnetic Compatibility (EMC): Radiated Emissions, Electrostatic Discharge and Radiated RF Susceptibility</i> |
| ○ <i>IEC 61010-1</i>             | <i>Safety Requirements for Electrical Equipment</i>   |
| ○ <i>IEC 60529</i>               | <i>Degrees of Protection Provided by Device Enclosures (IP Code)</i>  |
| ○ <i>IPC-A-610-G</i>             | <i>Acceptability of Electronic Assemblies: Class 2 Minimum</i>  |
| ○ <i>IPC-D-325A</i>              | <i>Documentation Requirements for Printed Circuit Boards and Assemblies</i>   |
| ○ <i>IPC-4552A</i>               | <i>Specification for Electroless Nickel/Immersion Gold (ENIG) Plating for Printed Circuit Boards</i>                    |
| ○ <i>IPC-A-620B</i>              | <i>Acceptance Requirements of Cable and Wire Harness Assemblies</i>   |
| ○ <i>IPC-7711B/7721B</i>         | <i>Rework, Repair and Modification of Electronic Assemblies</i>   |
| ○ <i>SDS</i>                     | <i>Safety Data Sheets: Applicable Documents Maintained on File</i>  |
| ○ <i>ISTA 1A</i>                 | <i>Packaging Impact: Drop Test Procedure ISTA 1A</i>  |

*Name and Title of Signatory:*

  
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*Daniel R. Moon, CEO & President, Prestan Products LLC*