



**PRESTAN**<sup>®</sup>

# Declaration of Conformity

## Quality Systems and Regulatory Compliance

Prestan is a developer and manufacturer of emergency medical training products. We employ a comprehensive set of processes and methods to ensure 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.

FDA GMP, Class I	FDA's Good Manufacturing Practices: Quality System Requirements
ANSI/ASQC Z1.4	Statistical Sampling Procedures and Tables for Inspection of Materials and Finished Goods
RoHS (2011/65/EU + 2015/863/EU)	Restriction of Hazardous Substances in Electronic Products and Components
Toxics In Packaging Act	(EU 94/62/EC) Restriction of Hazardous Substances in Packaging
UL94HB	Flammability Standard for Plastic Resins
EN 61326 / IEC 61326	Electro-Magnetic Compatibility (EMC): Radiated Emissions, Electrostatic Discharge and Radiated RF Susceptibility
IEC 61010-1	Safety Requirements for Electrical Equipment
IEC 60529	Degrees of Protection Provided by Device Enclosures (IP Code)
IPC-A-610-G	Acceptability of Electronic Assemblies: Class 2 Minimum
IPC-D-325A	Documentation Requirements for Printed Circuit Boards and Assemblies
IPC-4552A	Specification for Electroless Nickel/Immersion Gold (ENIG) Plating for Printed Circuit Boards
IPC-A-620B	Acceptance Requirements of Cable and Wire Harness Assemblies
IPC-7711B/7721B	Rework, Repair and Modification of Electronic Assemblies
SDS	Safety Data Sheets: Applicable Documents Maintained on File
ISTA 1A	Packaging Impact: Drop Test Procedure ISTA 1A

### Latex Status

Contact with products containing natural rubber has been associated with anaphylaxis in individuals allergic to natural rubber latex proteins. As such, Prestan has not designed any products made with natural rubber latex. Our suppliers certify that they have not produced or cross contaminated our products or its packaging with natural rubber latex.



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Prestan is also committed to managing the use of chemical substances in accordance with governmental regulations, industry standards, and customer-specific requirements to protect the environment. All our Training Manikins as well as our AED Trainers are compliant with the following:

### **EU RoHS Compliance Status**

*EU RoHS status is declared per Directive 2011/65/ EU and its subsequent amendments, including the Directive EU 2015/863 which additionally prohibited four phthalates. Homogeneous materials of parts that are compliant to this legislation have less than 0.1% by weight each of lead, mercury, hexavalent chromium, PBB, PBDE, DBP, BBP, DIBP, DEHP, and 0.01% by weight of cadmium.*

### **EU REACH SVHC Content**

*Substances of Very High Concerns (SVHCs) are declared if above 0.1% of the article per Regulation (EC) No. 1907/2006 and its subsequent amendments. The Candidate List of SVHCs is continually updated at <https://echa.europa.eu/candidate-list-table>.*

Name and Title of Signatory:

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