

Certificate of Conformity

Certificate No.: MD1202-09-01
Manufacturer: CENTRON TECHNOLOGIES CORP
319-25 SADANG-4-DONG DONGJAK-GU SEOUL, 156-823 KOREA
Authorized Representative: Genesis BPS International Srl
CP 2361, Route de St. Cergue 40A 1260 Nyon 2 Switzerland

This is to certify that the technical documentation for the product:

Product category: Tube Sealer
Model/type: SE640
Product description: Tube sealer seals a blood bag tubing using RF energy to prevent blood bag from leaking and any infection or contamination.
Classification: Class I according to Rule 12 of Annex IX, MDD 2007/47/IEC



Complies with the requirements applicable to it

The manufacturer's technical documentation, as required for Class I devices, has been assessed as meeting the Essential Requirements and relevant provisions of the Directive 93/42/EEC on Medical Devices for CE Marking.

Certificate issued by:

Soo Kil Park

Certification Manager
For UL Korea Ltd



HỮU TỊCH HĐQT
Nguyễn Hoàng Luân

Date: November 5, 2009

UL Korea Ltd
33rd Fl. Gangnam Finance Center,
737 Yeoksam-dong, Gangnam-gu,
Seoul, Korea

Telephone: +82 2 2009 9000



Any significant changes in design or construction of the product, or amendments to the Directive or Standards referenced above may render this receipt invalid. The product liability rests with the manufacturer or his representative in accordance with Council Directive 93/42/EEC.

While all due care and skill was exercised in carrying out this assessment, Underwriters Laboratories Inc. accepts responsibility only for proven gross negligence. This certificate is issued for the date that the technical documentation was reviewed. Conformance to all regulatory requirements is the sole responsibility of the manufacturer including the manufacture and quality control of the products. This is not legal document and cannot be used as such. This certificate remains the property of Underwriters Laboratories Inc. to whom it must be returned on request.

SAO Y BẢN CHÍNH
Ngày.....tháng.....năm 20.....



DECLARATION OF CONFORMITY

Type of Equipment: Tube Sealer
Brand Name/Trade Mark: -
Type Designation/Model: SE530, SE540
Manufacturer: Centron Corporation



In accordance with the following Directives:

2006/95/EC The Low Voltage Directive and its amending Directives
2004/108/EC The Electromagnetic Compatibility Directive and its amending Directives including amendments by the CE Marking Directive 93/68/EEC
2011/65/EU RoHS2 DIRECTIVE

CHỦ TỊCH HĐQT
Nguyễn Hoàng Tuấn

The following harmonized European standards or technical specifications have been applied:

EN 61010-1:2001 Safety requirements for electrical equipment for measurement, control, and laboratory use - Safety Part 1: General requirements
EN 61326-1:2006 Electrical equipment for measurement, control and laboratory use - EMC requirements Part 1: General requirements
EN 61000-3-2:2006 Electromagnetic compatibility (EMC). Limits for harmonic current emissions (equipment input current < 16 A per phase)
EN 61000-3-3:1995 +A1:2001 +A2:2005 Electromagnetic compatibility (EMC). Limitation of voltage changes, voltage fluctuations and flicker in public low voltage supply systems, for equipment with rated current <= 16 A/phase and not subject to conditional connection
EN 61000-4-2:1995 +A1:1998 +A2:2001 Electromagnetic compatibility (EMC). Testing and measurement techniques. Electrostatic discharge immunity test
EN 61000-4-3:2002 +A1:2002 Electromagnetic compatibility (EMC). Testing and measurement techniques. Radiated, radio-frequency, electromagnetic field immunity test
EN 61000-4-4:2004 Electromagnetic compatibility (EMC). Testing and measurement techniques. Electrical fast transient/burst immunity test
EN 61000-4-5:1995 +A1:2001 Electromagnetic compatibility (EMC). Testing and measurement techniques. Surge immunity test
EN 61000-4-6:1996 +A1:2001 Electromagnetic compatibility (EMC). Testing and measurement techniques. Immunity to conducted disturbances, induced by radio-frequency fields
EN 61000-4-11:2004 Electromagnetic compatibility (EMC). Testing and measurement techniques. Voltage dips, short interruptions and voltage variations immunity tests
IEC 62321:2008 Determination of levels of six regulated substances(lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers)
EN 50581:2012 Guiding Standard for Compliance with RoHS2 Requirements for Technical Documentation

The CE Marking on the products and/or their packaging signifies that Centron Technologies Corporation holds the reference technical file available to the European Union authorities.

Place and Date of Issue: Centron Corporation
44 Beolmal-ro, Dongan-gu, Anyang, Gyeonggi-do, 431-804 Korea
September 3, 2014

Authorized Signatory: Name: Luck Jean Sung
Title: President
Signature:

SAO Y BẢN CHÍNH
Ngày.....tháng.....năm 20.....



DECLARATION OF CONFORMITY

Type of Equipment: Tube Sealer
Brand Name/Trade Mark: -
Type Designation/Model: SE330, SE340
Manufacturer: Centron Corporation



CHỦ TỊCH HĐQT
Nguyễn Hoàng Tuấn

In accordance with the following Directives:

- 2006/95/EC The Low Voltage Directive and its amending Directives
- 2004/108/EC The Electromagnetic Compatibility Directive and its amending Directives including amendments by the CE Marking Directive 93/68/EEC
- 2011/65/EU RoHS2 DIRECTIVE

The following harmonized European standards or technical specifications have been applied:

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- EN 61326-1:2006 Electrical equipment for measurement, control and laboratory use - EMC requirements Part 1: General requirements
- EN 61000-3-2:2006 Electromagnetic compatibility (EMC). Limits for harmonic current emissions (equipment input current < 16 A per phase)
- EN 61000-3-3:1995 +A1:2001 +A2:2005 Electromagnetic compatibility (EMC). Limitation of voltage changes, voltage fluctuations and flicker in public low voltage supply systems, for equipment with rated current <= 16 A/phase and not subject to conditional connection
- EN 61000-4-2:1995 +A1:1998 +A2:2001 Electromagnetic compatibility (EMC). Testing and measurement techniques. Electrostatic discharge immunity test
- EN 61000-4-3:2002 +A1:2002 Electromagnetic compatibility (EMC). Testing and measurement techniques. Radiated, radio-frequency, electromagnetic field immunity test
- EN 61000-4-4:2004 Electromagnetic compatibility (EMC). Testing and measurement techniques. Electrical fast transient/burst immunity test
- EN 61000-4-5:1995 +A1:2001 Electromagnetic compatibility (EMC). Testing and measurement techniques. Surge immunity test
- EN 61000-4-6:1996 +A1:2001 Electromagnetic compatibility (EMC). Testing and measurement techniques. Immunity to conducted disturbances, induced by radio-frequency fields
- EN 61000-4-11:2004 Electromagnetic compatibility (EMC). Testing and measurement techniques. Voltage dips, short interruptions and voltage variations immunity tests
- IEC 62321:2008 Determination of levels of six regulated substances(lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers)
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