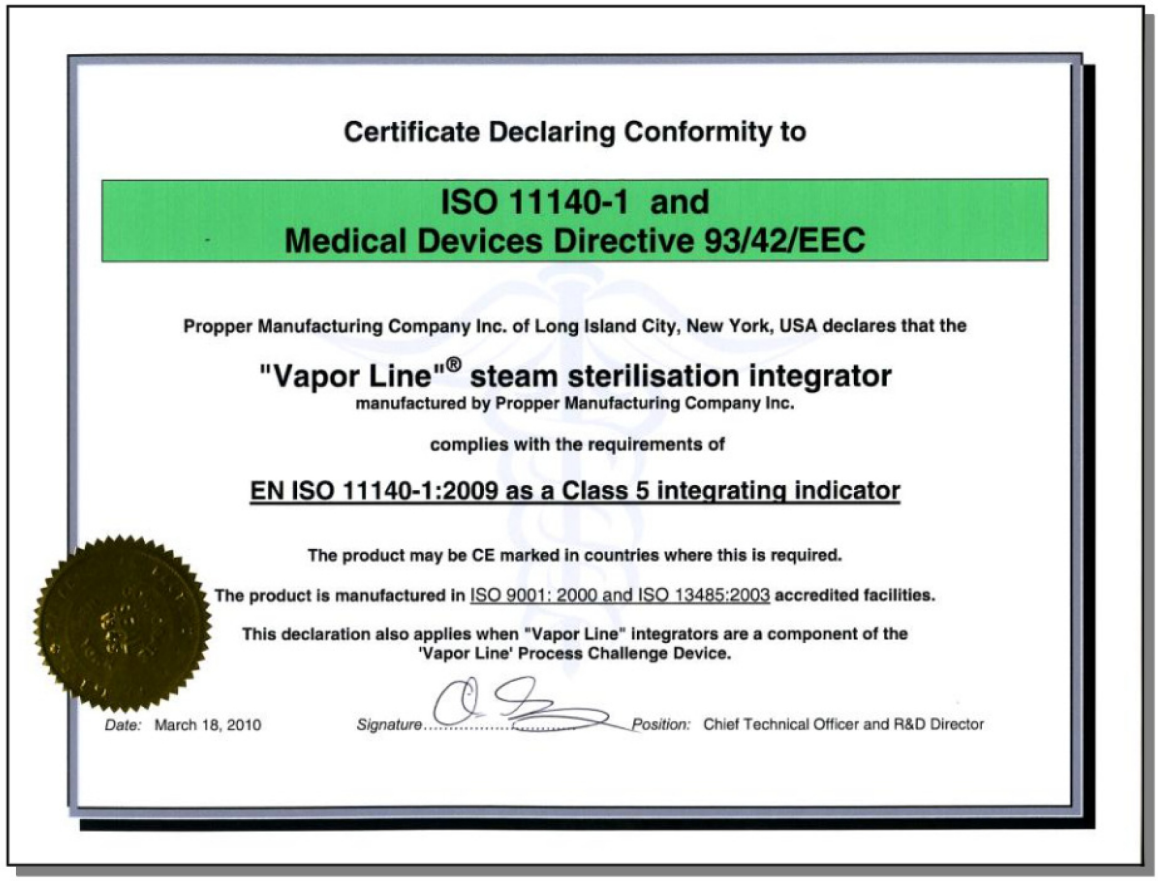


Certificate Declaring Conformity to

ISO 11140-1 and
Medical Devices Directive 93/42/EEC

Propper Manufacturing Company Inc. of Long Island City, New York, USA declares that the

"Vapor Line"® steam sterilisation integrator
manufactured by Propper Manufacturing Company Inc.

complies with the requirements of

EN ISO 11140-1:2009 as a Class 5 integrating indicator

The product may be CE marked in countries where this is required.

The product is manufactured in ISO 9001: 2000 and ISO 13485:2003 accredited facilities.

This declaration also applies when "Vapor Line" integrators are a component of the 'Vapor Line' Process Challenge Device.

Date: March 18, 2010 Signature..... Position: Chief Technical Officer and R&D Director

Dichiarazione di Conformità

TRADUZIONE

CERTIFICAZIONE DI CONFORMITA' A:
ISO 11140-1 - Direttiva Europea Dispositivi Medici 93/42/CEE

La sottoscritta Propper Manufacturing Company Inc. - Long Island City, New York - U.S.A.
dichiara che:

VAPOR LINE® INDICATORE INTEGRATORE PER STERILIZZAZIONE CON VAPORE
prodotto da Propper Manufacturing Company Inc.

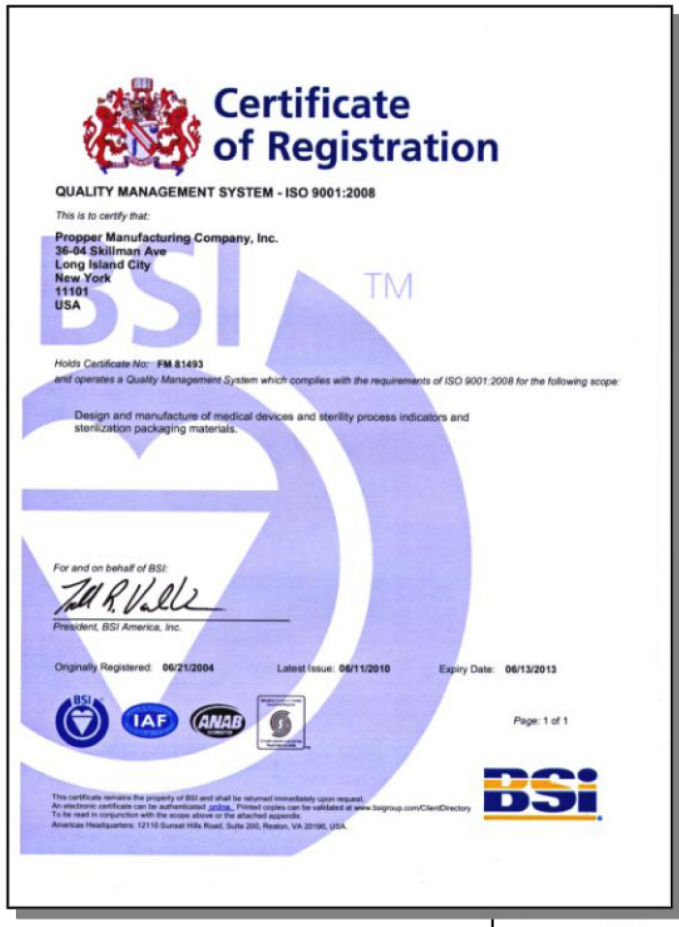
è conforme ai requisiti della Norma

EN ISO 11140-1: 2009 in qualità di Indicatore Integratore di Classe 5

Il prodotto può inoltre riportare il marchio CE nei Paesi in cui ciò venga richiesto.

L'articolo è prodotto in stabilimenti certificati ISO 9001: 2008 e ISO 13485: 2003.

Certificazioni ISO 9001: 2008 e ISO 13485: 2003



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2008

This is to certify that:

Propper Manufacturing Company, Inc.
36-04 Skillman Ave
Long Island City
New York
11101
USA

Holds Certificate No: FM 81493
and operates a Quality Management System which complies with the requirements of ISO 9001:2008 for the following scope:

Design and manufacture of medical devices and sterility process indicators and sterilization packaging materials.

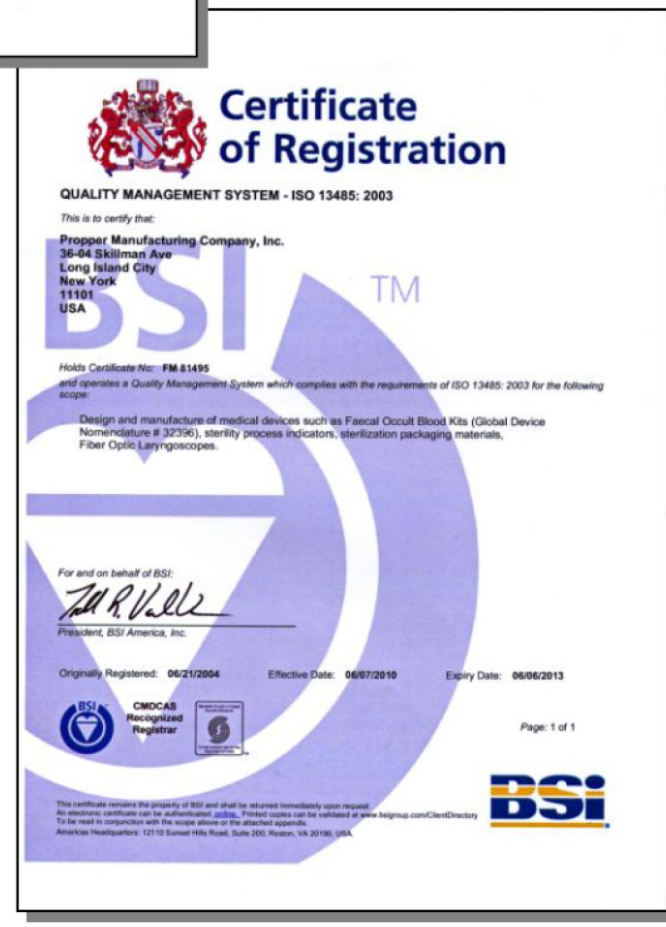
For and on behalf of BSI:

President, BSI America, Inc.

Originally Registered: 06/21/2004 Latest Issue: 06/11/2010 Expiry Date: 06/13/2013

Page: 1 of 1

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.
Americas Headquarters: 12110 Sunset Hills Road, Suite 200, Reston, VA 20190, USA.



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485: 2003

This is to certify that:

Propper Manufacturing Company, Inc.
36-04 Skillman Ave
Long Island City
New York
11101
USA

Holds Certificate No: FM 81495
and operates a Quality Management System which complies with the requirements of ISO 13485: 2003 for the following scope:

Design and manufacture of medical devices such as Faecal Occult Blood Kits (Global Device Nomenclature # 32396), sterility process indicators, sterilization packaging materials, Fiber Optic Laryngoscopes.

For and on behalf of BSI:

President, BSI America, Inc.

Originally Registered: 06/21/2004 Effective Date: 06/07/2010 Expiry Date: 06/06/2013

CMDCAS Recognized Registrar

Page: 1 of 1

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