

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.**CE 555682****Issued To:**

**Medline Industries, Inc.
Three Lakes Drive
Northfield
Illinois
60093
USA**

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2010-01-20**

Date: **2020-10-12**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Certificate No: CE 555682

Certificate Scope:

Manufacture of sterile gauze (x-ray and non-x-ray), lap sponges, wound drain systems, lubricating jelly and surgical gloves.

Manufacture of sterile and non-sterile fluid administration, management, and pressure monitoring devices and associated accessories.

Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of skin barrier film, examination gloves, surgical packs, surgeon gown packs, surgical drapes, bulb syringes, tubing, torque devices, closed systems tubing sets, guidewire introducers, and insertion tools.

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Supplementary Information to CE 555682

Issued To:

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NBOG codes (s)	Device description	Intended purpose
Class IIa		
MD 0101	Latex Surgical Gloves	N/A for class IIa devices
MD 0101	Synthetic Surgical Gloves (Polyisoprene; Neoprene; Polyisoprene / Neoprene Blend)	
MD 0301	X-ray gauze	
MD 0301	Laparotomy sponge	
MD 0108	Lubricating Jelly	
MD 0106	Wound drain	
MD 0102, MD 0106	Fluid Administration, management and pressure monitoring devices	
Class Is		
MD 0101	Examination Gloves	N/A for Class Is devices
MD 0101	Surgeon Gown Packs	
MD 0101	Surgical Drapes	
MD 0101	Surgical Packs	

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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NBOG codes (s)	Device description	Intended purpose
Class Is		
MD 0102	Bulb Syringes	N/A for Class Is devices
MD 0102	Closed systems tubing sets	
MD 0102	Tubing	
MD 0106	Guidewire Introducers	
MD 0106	Insertion Tools	
MD 0106	Torque devices	
MD 0301	Gauze / ABD Pads / Non-woven swabs	
MD 0303	Skin Barrier Film	

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