



By Royal Charter

EC Certificate - Production Quality Assurance

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

No.

CE 597089

Issued To:

**Medline International France SAS
5, rue Charles Lindbergh
Chateaubriant
44110
France**

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):



First Issued: **2013-07-17**

Date: **2019-06-14**

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

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Page 1 of 4

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.

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.

Certificate No: CE 597089

Certificate Scope:

Those aspects of manufacturing relating to obtaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Devices Directive.

Those aspects of manufacture related to maintaining and securing sterility of surgical drapes, surgical gowns, table covers, surgical towels, instrument and equipment covers, plastic bone cement mixing bowls and spatulas, plastic cautery holsters and patient plastic devices and sets (cups and lids, bowls and lids, basins and lids, trays and pitchers) and surgical skin markers and rulers, sterile towel and drape clamp, eye shield, bulb syringe, plastic clamp (flow control), sponge sticks for skin disinfection, plastic forceps and clamps (support for skin disinfecting), suction tubing, umbilical cord clamp, eye wick, crepe bandage and skin closure strip.

First Issued: **2013-07-17**Date: **2019-06-14**Expiry Date: **2024-05-26****...making excellence a habit.™**

Page 2 of 4

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Supplementary Information to CE 597089

Issued To:

Medline International France SAS
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Number	Device Name	Intended purpose per IFU
Class Is		
MDS7006	Custom procedure pack	NA for class Is devices
MDS7006	Surgical Gowns	NA for class Is devices
MDS7006	Surgical Drapes	NA for class Is devices
MDS7006	Table Covers	NA for class Is devices
MDS7006	Surgical Towels	NA for class Is devices
MDS7006	Instrument and Equipment Covers	NA for class Is devices
MDS7006	Plastic Bone Cement mixing with Spatulas	NA for class Is devices
MDS7006	Plastic Cautery Holsters	NA for class Is devices
MDS7006	Patient Plastic (Cups and lids, bowls and lids, basins and lids, trays and Pitchers)	NA for class Is devices
MDS7006	Surgical Skin markers and Rulers	NA for class Is devices
MDS7006	Sterile towel and drape clamp	NA for class Is devices
MDS7006	Eye Shield	NA for class Is devices
MDS7006	Bulb Syringe	NA for class Is devices

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Page 3 of 4

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Number	Device Name	Intended purpose per IFU
Class Is		
MDS7006	Plastic Clamp (Flow Control)	NA for class Is devices
MDS7006	Sponge sticks for skin disinfection	NA for class Is devices
MDS7006	Plastic forceps and clamps (support for skin disinfecting)	NA for class Is devices
MDS7006	Suction tubing	NA for class Is devices
MDS7006	Umbilical cord clamp	NA for class Is devices
MDS7006	Eye wick	NA for class Is devices
MDS7006	Crepe bandage	NA for class Is devices
MDS7006	Skin closure strip	NA for class Is devices

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Page 4 of 4

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