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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2013-07-17** Date: **2021-04-16** Expiry Date: **2024-05-26**

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By Royal Charter

Certificate No: CE 597089

Certificate Scope:

The manufacture of sterile wound protector drapes.
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 Annex V relating to metrology in the manufacture of measuring cannisters.
Those aspects of manufacture related to maintaining and securing sterility of drape packs and accessories, 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 and accessories,umbilical cord clamp, eye wick, crepe bandage, skin closure strip and instrument pads.

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Supplementary Information to CE 597089

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Number	Device name	Intended purpose per IFU
Class IIa		
MD 0303	Wound Drape	N/A for Class IIa devices
Number	**Device Name**	**Intended purpose per IFU**
Class Is		
MD0101	Custom procedure pack	NA for class Is devices
MD0101	Surgical Gowns	NA for class Is devices
MD0101	Surgical Drapes	NA for class Is devices
MD0101	Table Covers	NA for class Is devices
MD0101	Surgical Towels	NA for class Is devices
MD0101	Instrument and Equipment Covers	NA for class Is devices
MD0106	Plastic Bone Cement mixing with Spatulas	NA for class Is devices
MD0106	Plastic Cautery Holsters	NA for class Is devices
MD0106	Patient Plastic (Cups and lids, bowls and lids, basins and lids, trays and Pitchers)	NA for class Is devices
MD0106	Surgical Skin markers and Rulers	NA for class Is devices
MD0101	Sterile towel and drape clamp	NA for class Is devices

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Device code	Device name	Intended purpose per IFU
Class Is		
MD0105	Eye Shield	NA for class Is devices
MD0102	Bulb Syringe	NA for class Is devices
MD0102	Plastic Clamp (Flow Control)	NA for class Is devices
MD0106	Sponge sticks for skin disinfection	NA for class Is devices
MD0106	Plastic forceps and clamps (support for skin disinfecting)	NA for class Is devices
MD0102	Suction tubing and accessories	NA for class Is devices
MD0106	Umbilical cord clamp	NA for class Is devices
MD0105	Eye wick	NA for class Is devices
MD0301	Crepe bandage	NA for class Is devices
MD0303	Skin closure strip	NA for class Is devices
MD0101	Instrument Pads	NA for class Is devices

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Number	Device Name	Intended purpose per IFU
Class Im		
MD 0104	Measuring Cannister	N/A for class Im device

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