

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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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:

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

Issued To:

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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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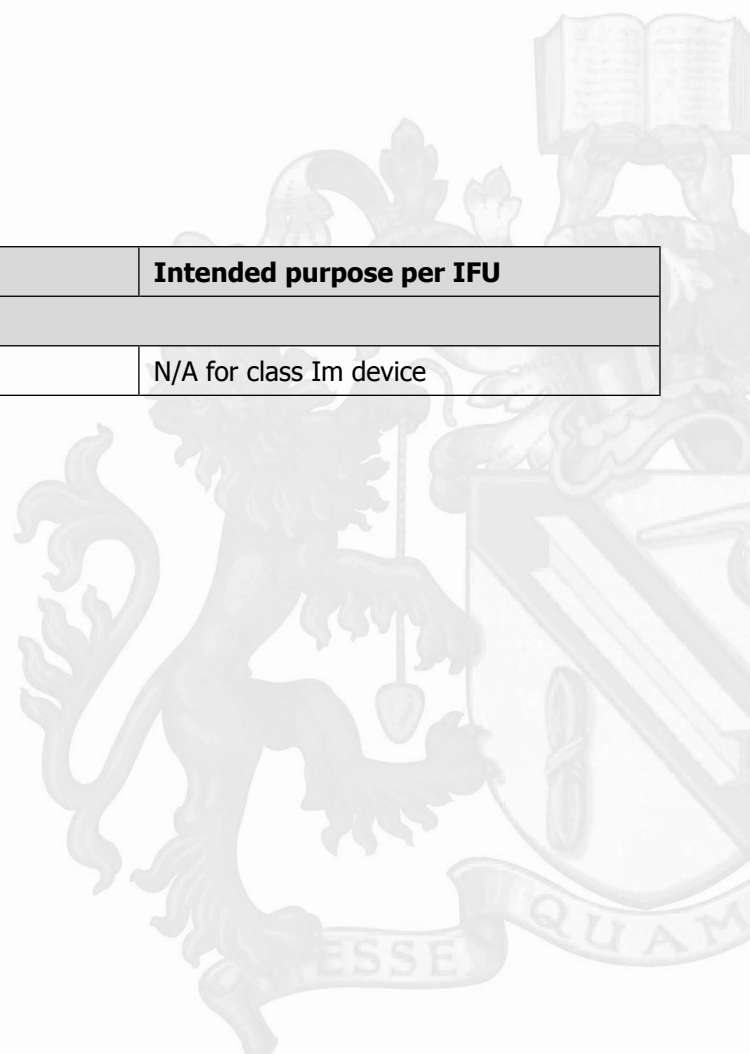
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Supplementary Information to CE 597089

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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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Date	Reference Number	Action
17 July 2013	7990330	Transfer from another Notified Body, TÜV; Previous Certificate Reference G2S 11 05 77203 002 and G2S 11 05 77203 003. First issue
17 December 2013	8081333	Addition of subcontractors Jie Gao Plastic Products Co., Ltd, Dongguan City, Guangdong Province, China; S.E.S Healthcare Products Co., Ltd. Lingbi Development Zone, Lingbi City, China, Perfect Healthcare (Shandong) Co., Ltd, Yutai Economy Development Zone, Shandong, China and Emerald Nonwovens International Co., Ltd, T. Nong Chumpon Nuan, Kao-Yoi, Petchaburi 76140, Thailand. Removal of subcontractors Suzhou Andersen Non-woven Products Co., Ltd, Xiangcheng District, Suzhou, China and proMEDICAL Products Co., Ltd, New North District, Changzhou, China. Correction address of existing subcontractor Master & Frank Enterprise Co., Ltd. to Dongguan Shin Yi Healthcare Products Factory, Banhu industrial District, Huang Jiang, Dong Guan City, Guan Dong Province China.
	8081334	Extension to scope to add patient plastics (cups and lids, bowls and lids, basins and lids, trays and pitchers)

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Date	Reference Number	Action
06 February 2014	8108111	Addition of subcontractors Xuchang Zhengde Environstar Medical Products Co., Ltd., Xuchang City, Henan Province, China and removal of subcontractor Shaoxing ZhengDe Surgical Dressing Co., Ltd, Shaoxing, Zhejiang, China
02 July 2014	8110357	Certificate renewal
28 August 2014	8208783	Address change of subcontractor S.E.S Healthcare Products Co., Ltd.
26 January 2015	8268115	Addition of subcontractor F.P.S.A. Fonderie Et Plasturgie SA, Oyonnax, France.
24 April 2015	8291942	Extension to scope to add plastic bone cement mixing bowls and spatulas, plastic cautery holsters. Addition of subcontractors Lianyungang Aiyeh Non-Woven Products Co., Ltd., Lianyungang, Peoples Republic of China and LianYunGang Bronco Medical Supply Co., Ltd., Lianyungang, Peoples Republic of China.

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16 December 2015	8422484	Addition of subcontractors Suzhou SKO Plastics, Suzhou, China, Jiangsu Province JianErKang Medical Dressing, Jiangsu, China, Ebster, Velka Bites, Czech Republic, Medline Slovakia, Slovakia and SES Healthcare Products (Lingbi) Co., Ltd, Shouxian City, China. Deletion of subcontractor Master & Frank Enterprise Co., Ltd., Banhu Industrial District, Dong Guan City, China. Scope extension to add insufflation tubing with filters.
17 February 2016	8481264	Addition of subcontractor Fengyang Jiehong Nonwoven Product Co., Ltd., Fengyang City, China for the manufacture of surgical gowns.
25 August 2016	8588093	Change of name from Ebster s.r.o. to Steris AST s.r.o. Removal of subcontractors F.P.S.A and Jie Gao Plastic Products.
25 November 2016	8647252	Addition of subcontractor Productos Medline S.A. de C.V. Tamaulipas, Mexico for the manufacture of procedure packs, Midwest Sterilisation Corporation, Laredo, Texas for ETO sterilisation of procedure packs and Lianyungang Bronson Non-woven Co., Ltd for manufacture of drapes of gowns.

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16 February 2017	8689092	Extension of scope to include sterile skin barrier film. Addition of subcontractors Finesse Medical Ltd, Longford, Ireland, Synergy Health Westport Ltd, County Mayo, Ireland and S.E.S Healthcare Products (Hefei) Co., Ltd., Jinzang Road, Hefei, China.
10 July 2017	8744832	Removal of subcontractors Raguse and Suzhou SKO Plastics Co. Ltd. Update to subcontractor names for PingDingShan JoinKona Medical Products Co. Ltd to Henan JoinKona Medical Products Stock Co. Ltd. And from BDF to Guardian.
21 December 2017	8872171	Addition of subcontractor Suzhou Addison Non-woven Product Co., Ltd. Tongcheng Road, Suzhou, China for manufacture of drapes and gowns.
18 January 2018	8889802	Readdition of manufacturing subcontractor Suzhou Addison Non-Woven, Yuanhe Town, Suzhou, China, to correct administrative error.
20 August 2018	8996872	Scope extension to add skin markers and rulers. Addition of subcontractors Shanghai Everpure Medical Plastic Co. Ltd (Seblyne) and Allmed Medical Products Co., Ltd for manufacture and Changshu Rozer Sterilization Technology Co. Ltd and Allmed Medical Products Co., Ltd for ETO sterilisation. Scope clarification for instrument and equipment covers. Synergy Health Westport activity updated to Gamma Sterilization.

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Date	Reference Number	Action
04 March 2019	8412146	Traceable to NB 0086.
14 June 2019	9685863	<p>Certificate Renewal.</p> <p>Inclusion of product information table.</p> <p>Removal of 'Insufflation tubing with filters,' Skin Barrier Film' and 'the manufacture and final inspection of sterile procedure packs' from scope.</p> <p>Clarification added to patient plastic devices in scope.</p> <p>Addition of 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, skin closure strip to scope expression.</p> <p>Removal of the following subcontractors: Excellent Medical Products, Finesse Medical Limited, Guardian (Patna Ayrshire), Guardian (Girvan Ayrshire), Henan JoinKona Medical Products Stock Co. Ltd., Midwest Sterilization Corporation, Perfect Healthcare (Shandong) Co., Ltd., Productos Medline S.A de C.V, Synergy Health Westport Limited & Suzhou Avon Textiles.</p> <p>Correction to Master & Frank (Pinghu) to include provision of ETO sterilization services.</p> <p>Update to address of Sterigenics Belgium (Petit-Rechain) & Xuchang Zhengde Environstar Medical Products Co., Ltd.</p> <p>Addition of subcontractors Sterylene & Yong Chang Sterilization China Co., Ltd. for the provision of Ethylene Oxide Sterilization.</p>

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Date	Reference Number	Action
12 December 2019	3069739	Addition of sterile drape packs and accessories to existing scope expression. Extension to scope to add metrology aspects for the manufacture of measuring cannisters. Addition of manufacturing subcontractor Suzhou Jinsheng Plastic Co., Ltd. Removal of manufacturing subcontractor Suzhou Addison Non-Woven Product Co., Ltd (N°168, Litai Road). Addition of ETO sterilization services to Dongguan Hongde Medical Plastic Products Co.
25 April 2020	3166866	Addition of significant subcontractor Cobes Industries (Myanmar) Company Limited for manufacture and ETO sterilization.

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03 July 2020	3250931	<p>Addition of subcontractor Lianyungang Anson Non-woven Product Co., Ltd. for manufacture of surgical drapes, surgical gowns and draping packs.</p> <p>Addition of ETO Sterilization Subcontractor Dongguan Shin Yi Healthcare Products Factory, No 54 Hong Sheng Road, Diao Lang Village, Huang Jiang Town, Dong Guan City, Guan Dong Province. 523750 China.</p> <p>Removal of ETO Sterilization subcontractor Master & Frank Ent. Co., Ltd, Ban Hu Industry, Huang Jiang Town, Dong Guan City, Guang Dong Province 523753 China.</p> <p>Update to company name of Master & Frank (Pingu) Ent. Co., Ltd. to Principle and Will Biotech (Pinghu) Co., Ltd together with an administrative update to the address.</p> <p>Administrative update to address of Master & Frank Enterprise Co., Ltd. Dongguan Shin Yi Healthcare Products Factory.</p>
03 December 2020	3331593	<p>Update to certificate scope expression to add Instrument Pads; Addition of manufacturing subcontractor GCMedica Enterprise Ltd. (WUXI); Removal of sterilization subcontractor Synergy Health AST Venlo; Inclusion of Class Is Instrument Pads in supplementary table and update to NBOG codes of all Class Is devices in line with current guidance.</p>
19 January 2021	3367327	<p>Addition of manufacturing subcontractor Xuchang Zhengde Environstar Medical Products Co., Ltd. site at Area B, Baihua Road East.</p>

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Date	Reference Number	Action
22 February 2021	3388000	Addition of scope expression Manufacture of sterile wound protector drapes. Addition of device to supplementary information table.
16 April 2021	3409278	Update to certificate scope expression to include suction tubing accessories Addition of ethylene oxide sterilization to services supplied by Xuchang Zhengde Environstar Medical Products Co., Ltd. Weilai Road site
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
24 November 2021	3552145	Update to significant subcontractor listing Removal of ethylene oxide sterilization from Principle and Will Biotech (Pinghu) Co., Ltd. Addition of Joykey Industrial (Ping Hu) Limited for provision of ethylene oxide sterilization Addition of SES Healthcare products Co., Ltd facility at South of Qishi Road, Lingbi for manufacture Update name of ethylene oxide sterilization subcontractor Sterylene to Ionisos SAS Update name of ethylene oxide sterilization subcontractor Synergy Health (Suzhou) Sterilization Technologies Ltd to Steris Sterilization Technologies (Suzhou) Ltd.

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Date	Reference Number	Action
30 March 2022	3498501	<p>Addition of the following significant subcontractors: Medline Assembly Slovakia s.r.o for manufacture Qingdao Changlong Stationery Co., Ltd. for manufacture Suzhou Jingle Polymer Medical Apparatus Co., Ltd. for manufacture</p> <p>Removal of the following significant subcontractors: Allmed Medical Products Co., Ltd. located at You Yi Road and Jin Shan Road Majiadian Town, Zhijiang City in China</p>
26 July 2022	3734593	<p>The following class Is devices are removed from the scope of the certificate: surgical towel, 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 disinfection), umbilical cord clamp, eye wick, crepe bandage and skin closure strips</p> <p>Removal of significant subcontractor Jiangsu Province JianErKang Medical Dressing Co., Ltd. for manufacture and ethylene oxide sterilization</p>
10 January 2023	3775314	Addition of subcontractor for ethylene oxide sterilization

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10 January 2023

Medline International France SAS
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To whom it may concern,

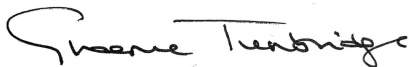
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 597089	93/42/EEC Annex V	3775314	Addition of subcontractor for ethylene oxide sterilization of procedure packs

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,



Graeme Tunbridge
Senior Vice President, Medical Devices