



EC Certificate - Production Quality Assurance

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

No. CE 504677

Issued To: Lifestream Purification Systems LLC

7303 Burleson Rd., Suite 801

Austin Texas 78744 USA

In respect of:

The manufacture of colonic irrigation systems and of sterile colon irrigation nozzles and flex tubes

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

Gay C Stade

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

First Issued: **2006-05-22** Date: **2020-12-17** 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.





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Supplementary Information to CE 504677

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1101	Colonic irrigation system	N/A
MD 0102	Non-active devices for injection, infusion, transfusion and dialysis, connected to irrigation system	N/A

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 504677**Date: **2020-12-17**

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Austin Texas 78744 USA

Subcontractor:

Service(s) supplied

ConMed Corporation 525 French Road Utica New York 13502

USA

Finished Device Supplier

Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands **EU Representative**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No:

CE 504677

Date:

2020-12-17

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Date	Reference Number	Action
22 May 2006		First issue
26 May 2011	7645610	Certificate renewal. The addition of Emergo Europe as the EU representative
01 April 2012	7816423	Re-issue due to company address change from "2001 South Lamar Blvd., Suite G, Austin, Texas 78704, USA" to "7303 Burleson Rd., Suite 801, Austin, Texas 78744, USA"
24 March 2016	8438045	Certificate renewal Combining OBL certificate CE 575630 with this certificate, therefore:
		1. Addition of the sterile colon irrigation nozzles and flex tubes to the scope
		2. Addition of significant subcontractor "ConMed Corporation" as finished device supplier
05 February 2019	7781910	Traceable to NB 0086.
Current	3281142	Renewal, added Class IIa device table, and changed EU Representative Emergo Europe's address from "Molenstraat 15 2513 BH The Hague, The Netherlands" to "Prinsessegracht 20, 2514 AP The Hague, The Netherlands."

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