

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.****CE 595587**

## Issued To:

**LUMEDX Corporation  
555 12th St., Suite 2060  
Oakland  
California  
94607  
USA**

In respect of:

**Design and manufacture of Cardiovascular Information Systems.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 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: **2013-05-10**Date: **2019-02-28**Expiry Date: **2023-05-09**

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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.

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.

# EC Certificate - Full Quality Assurance System

## Certificate History

Certificate No: **CE 595587**  
 Date: **2019-02-28**  
 Issued To: **LUMEDX Corporation**  
**555 12th St., Suite 2060**  
**Oakland**  
**California**  
**94607**  
**USA**

Date	Reference Number	Action
10 May 2013	7945736	First Issue
16 July 2015	8344780	Change of subcontractor name from LUMEDX Corporation to Lumedx Healthcare Technologies (I) Pvt. Ltd. and address to 601, Indoglobal Software Technology Park, Plot no. 41, Rajiv Gandhi Infotech Park, Phase-1, Hinjewadi, PUNE – 411057.
7 March 2018	8869180	Renewal
28 February 2019	8886827	Traceable to NB 0086.
<b>Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3</b>		
07 December 2022	3701139	Legal Manufacturer Name and Address Change. Removal of subcontractor listings.

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

07 December 2022

LUMEDX Corporation  
 LumedX - An Intelerad Company  
 305 Church at N Hills Street  
 Floor 6 Raleigh  
 North Carolina  
 27609  
 USA

To whom it may concern,

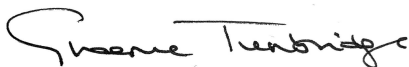
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26<sup>th</sup> May 2021.

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 595587	93/42/EEC Annex II excluding Section 4	3701139	Change in legal manufacturer name and address from "LUMEDX Corporation, 555 12th St., Suite 2060 Oakland California 94607 USA" to "LUMEDX Corporation LumedX - An Intelerad Company, 305 Church at N Hills Street Floor 6 Raleigh North Carolina 27609 USA" Removal of subcontractor listings.

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