

EC Certificate - Full Quality Assurance System

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

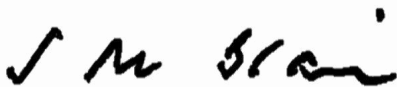
No. CE 595587
Issued To: **LUMEDX Corporation**
555 12th St., Suite 2060
Oakland
California
94607
USA

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 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2013-05-10**

Date: **2018-03-07**

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.

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

List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	EU Representative
LUMEDX Corporation 110, 110th Ave NE Suite 475 Bellevue Washington 98004 USA	Design Manufacture
LUMEDX Healthcare Technologies (India) Pvt. Ltd. 601, Indoglobal Software Technology Park Plot no. 41, Rajiv Gandhi Infotech Phase-1, Hinjewadi, PUNE 411057 India	Design Manufacture

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: CE 595587
Date: 2018-03-07
Issued To: LUMEDX Corporation
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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.
Current	8869180	Renewal

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