

EC Certificate - Full Quality Assurance System

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

No. CE 694929
Issued To: **Oxylitre Holdings Limited**
Morton House
Skerton Road, Old Trafford
Manchester
M16 0WJ
United Kingdom

In respect of:

Design and manufacture of; Pressure regulators, Pipeline flow meters, Pipeline hoses and fittings, Pipeline suction units, Electrical mobile suction pumps, Injector suction systems, Portable battery suction pumps; Entonox demand systems for pain relief, Attachments and components for medical use.
Those aspects of Annex II related to metrology in the design and manufacture of jar systems for medical suction pumps.

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):



Albert Roossien, Regulatory Lead

First Issued: **2018-06-15**

Date: **2019-02-13**

Expiry Date: **2023-06-14**

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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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Certificate History

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Date	Reference Number	Action
15 June 2018	8956564	First issue. Devices previously covered by EC certificate CE 659692 (Oxylitre Ltd.). New certificate issued due to legal entity change.
08 January 2019	9670972	Correction to Company name.
Current	8956566	Traceable to NB 0086.

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