

# EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

**No.** CE 697395  
**Issued To:** **DEVICARE S.L.**  
**Av. Can Domènech, s/n**  
**Eureka Building**  
**UAB Research Park**  
**Cerdanyola del Vallès**  
**Barcelona**  
**08193**  
**Spain**

In respect of:

**The design and manufacture of the Lit-Control pH meter for self-testing and self-monitoring of urological pathologies related to urine acid-base balance.**

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex IV, the quality system was found to meet the requirements of 98/79/EC Annex IV.

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: **2020-07-14**

Date: **2020-07-14**

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. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.

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

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## Supplementary Information to CE 697395

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NBOG Code	Device Name	Intended Purpose
<b>Self-test</b>		
IVD 0401	Lit-Control pH Meter  LT0033 (Spanish-Portuguese)  LT0001 (English-French)	Lit-Control pH Meter is a self-testing and self-monitoring medical device that allows the urinary pH monitoring for the control and/or treatment of urological pathologies related to the urine acid-base balance, such as renal lithiasis, calcifications of urinary catheters, cystitis, urinary tract infections, painful bladder syndrome and overactive bladder, among others.

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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.

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## List of Significant Subcontractors

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

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**Spain**

**Subcontractor:**

**Service(s) supplied**

IDNEO Technologies S.A.U.  
Pol. Ind. Can Magarola  
C/ Rec de Dalt 3  
ES-08100 Mollet del Vallès  
Barcelona  
Spain

**Manufacture**

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# EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 697395**  
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Date	Reference Number	Action
Current	9626970	First issue

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.

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