By Royal Charter

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex III Section 6

No. **CE 630970**

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 of the design relating to the device under the requirements of Council Directive 98/79/EC, Annex III Section 6, the design of the device conforms to the requirements of 98/79/EC.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2015-12-14** Date: **2019-02-08** Expiry Date: **2020-12-13**

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Supplementary Information to CE 630970

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Certificate History

Date	Reference Number	Action
14 December 2015	8284978	First Issue
18 November 2016	8621772	Review of changes related to the removal of the liquid level detector.
17 February 2017	8681990	Extension to intended use claim to include additional urological pathologies.
8 January 2018	8860053	Labelling change for the addition of French and Portuguese.
Current	8764583	Traceable to NB 0086.

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