

EC Certificate - Full Quality Assurance System

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

No.**CE 681105****Issued To:**

**SOFTWARE NEMOTEC SL
AV. JUAN CARAMUEL 1
LEGANÉS
Madrid
28919
Spain**

In respect of:

Those aspects of Annex II related to metrology in the design and manufacture of planning software for dentistry

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: **2019-04-02**

Date: **2019-10-24**

Expiry Date: **2024-04-01**

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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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Supplementary Information to CE 681105

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NBOG Code	Device Name	Intended purpose per IFU
Class Im		
MD 1111	NemoStudio	NemoStudio is a suite of modules that allows import/capture, storage, analysis, treatment plan and presenting/reporting of all those patients and their records.

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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.

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Certificate History

Certificate No: **CE 681105**
Date: **2019-10-24**
Issued To: **SOFTWARE NEMOTEC SL**
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Madrid
28919
Spain

Date	Reference Number	Action
02 April 2019	8800567	First issue.
Current	9785590	Manufacturer address changed from "Calle Juan de la Cierva 66, Arroyomolinos, Madrid, 28939, Spain" to "Av. Juan Caramuel 1, Leganés, Madrid, 28919, Spain"

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