

EC Certificate - Full Quality Assurance System

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

No. **CE 664137**
Issued To: **Kvikna ehf**
Storhofdi 21
110 Reykjavik
Iceland

In respect of:

Design and manufacture of software intended for use in clinical EEG.

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: **2017-04-27**

Date: **2019-02-26**

Expiry Date: **2022-04-26**

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Page 1 of 1

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

Certificate No: **CE 664137**
Date: **2019-02-26**
Issued To: **Kvikna ehf
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Date	Reference Number	Action
27 April 2017	8638335	First issue.
Current	8893352	Traceable to NB 0086.

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Page 1 of 1

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

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