By Royal Charter

# 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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2017-04-27** Date: **2017-04-27** Expiry Date: **2022-04-26**

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# EC Certificate - Full Quality Assurance System Certificate History

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| Date | Reference Number | Action |
|---|---|---|
| 27 April 2017 | 8638335 | First issue. |

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