



EC Declaration of Conformity

Kvikna Medical ehf confirms that the Stratus EEG software bears the CE marking, has been designed and manufactured under the control of EN ISO 13485:2016 and meets the essential requirements of Annex I of the Medical Device Directive 93/42/EEC with its five amendments from 1998-2007.

The Stratus EEG software is classified as a Class IIa device in accordance with rule 10 of Annex IX of MDD 93/42/EEC.

EC Certificate Number: 664137 first issued by BSI Group on April 27th 2017.

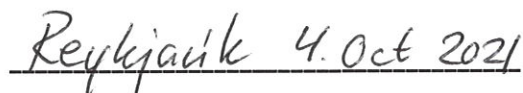
The Stratus EEG software has been tested and conforms to the following specifications:

EN 62304:2006/AMD 1:2015	Medical device software – Software life cycle processes.
EN 14971:2019	Medical devices – Application of risk management to medical devices.
EN 62366-1:2015/AMD1:2020	Medical devices – Part 1 – Application of usability engineering to medical device.
EN 82304-1:2016	Health software – Part 1: General requirements for product safety.
EN 80601-2-26:2019	Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs.

For and on behalf of the manufacturer,

A handwritten signature in black ink, appearing to read "Garðar Þorvarðsson", is written over a horizontal line.

Garðar Þorvarðsson, CEO

A handwritten signature in black ink, appearing to read "Reykjavík 4. Oct 2021", is written over a horizontal line.

Place and Date of Issue