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CE

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,

Garðar Þorvarðsson

Garðar Þorvarðsson, CEO

Reykjavík 4. Oct 2021

Place and Date of Issue