



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 requirements of the Medical Device Regulation (MDR 2017/745), including the General Safety and Performance Requirements of Annex I.

The intended use of the Stratus EEG software is:

The Stratus EEG is an EEG system that allows acquisition, display, archive, storage and analysis of physiological signals. The intended user of this product is a qualified medical practitioner trained in electroencephalography who will exercise professional judgment in using the information. The Stratus EEG system also includes the display of a quantitative EEG plots, power spectrum, which is intended to help the user to monitor and analyze the EEG. This device does not provide any diagnostic conclusion about the patient's condition to the user.

The Stratus EEG software is classified as a class IIa device in accordance with rule 11 of Annex VIII of the MDR 2017/745.

The Stratus EEG software bears the following Basic UDI-DI: 569411001QX

MDR Certificate Number: 747371 issued by BSI Group (2797) on June 12th 2023 based on a quality management system and assessment of technical documentation (Annex IX of the MDR 2017/745).

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 devices.
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.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

For and on behalf of the manufacturer,

Reykjavík 19.6.2023

Place and Date of Issue

Garðar Þorvarðsson

Garðar Þorvarðsson, CEO