X-System
INTELLIGENT MUSIC

UK DECLARATION OF CONFORMITY

We ensure and declare that the X-System medical software is in accordance with Part ll, Regulation 7 of the UK Medical Device Regulations - SI 2002 : 618, as amended, is classified as a class l device. The software is design and supplied to a quality management system meeting the requirements of the following standards - BS ISO 9001-2015 and BS ISO 13485-2016 and that the application of the system as required by annex II article 3.2 ensure they comply with the requirements of the Medical Devices Regulations SI 2002 : 618, as amended. We confirm that the Essential Safety Requirements of Annex l have been demonstrated.

The scope of the software is the design and supply of medical software using audification of electrical brain activity to entrain neurophysiological activity.

The UK Declaration of Conformity is issued under the sole responsibility of the manufacturer.

The above is confirmed by the assessments undertaken by the certification body listed below:-

Certificate Number - Full Quality Assurance System - 23/17930
A Cube TIC Ltd., Certification Body No. 0273
Unit 5, Middle Bridge Business Park,
Bristol Road,
Portishead,
BS20 6PN

Signed for and behalf of
X-System Ltd.

Michael Waters
Managing Director

Rev. 01 - 31/07/2023