

Statement of Comformance

We declare that the:

Apple iPad mini

Including: Accessories

comfirms to the Medical Device Directory 93/42/EEC and follows standard NS-EN 12182:1999 Technical aids for disabled persons-General requirements and test methods, EN 60601-1 Medical electrical equipment Part 1: General requirements for safty and EN 60601-1-2 Medical electrical equipment Part 1: General requirements for safty -1 Colleteral standard: Electromagnetic compatibility- Requirements and test.

Risk analysis has also been done according to NS-EN 14971 Medical Device-Application of risk management to medical devices.

Kolbotn 4/5 - 2015

Gewa AS