RE: CE Declaration

To Whom it May Concern,

Class 1 medical device manufactures are not required to have a CE certificate but rather follow the procedure referred to in the Medical Device Regulation 2017/745 and draw up a Declaration of Conformity. Class 1 medical devices are required to be registered with the competent authority of the member state in which the manufacturer is based.

Our Irish Medical Board registered general device registration number is;

IE/CA01/M/GM/0562

Issued by:_____ Date: 08/06/2022

Rebecca Holmes
Senior Quality Specialist