To Whom It May Concern

In the matter of CE Certificate:

Class 1 medical device manufacturers are not required to have a CE certificate but rather follow the procedure referred to in Annex V11 Medical Device Directives 93/42 EEC and draw up a Declaration of Conformity. Class 1 devices are required to be registered with the Competent Authority of the Member State in which the manufacturer is based.

A copy of our HPRA Registration Number: IE/CA01/M/GM/0562 is furnished herewith this declaration.

Signed: Michelle Dempsey Date: 2/Mar/2020

Michelle Dempsey
Quality Manager