



Declaration of Conformity

Manufacturer:

PaxeraHealth Corporation

85 Wells Ave, Suite 120 Newton, MA. 02459, USA,

We hereby, PaxeraHealth Corporation, declare under our sole responsibility that the following products of class (I):

Paxera Medical Imaging Software: PaxeraPACS (PaxeraUltima360, PaxeraView, iPaxera).

Has been tested, checked and certified by the “European Authorized Representative Center Obelis s.a” to be complying with the listed standards and in conformity with the technical provisions of **Annex II — article 14.2 of the European directive MDD 93/42/EEC of class (I) medical devices**. The examination of the mentioned products has been carried out following the requirements of the **international standard IEC 62304 of medical device software** and with the national legislations based upon them.

Manufactures confirms that all provisions are met, which ensures that all products introduced to the market conform to the technical documentation and basic requirements of aforementioned directive(s).

Authorized Signatory:

Date: 12. 07. 2023.

Mike George

Chief operations officer

