Exact Imaging Inc. - Person Responsible for Regulatory Compliance

I, Gwendolyn Pinto, Director, RA & QA of Exact Imaging Inc., hereby declare that irrespective of my other duties at Exact Imaging, I assume the responsibility and authority of Person Responsible for Regulatory Compliance (PRRC) under Article 15 of Regulation (EU) 2017/745 – Medical Device Regulations (EU MDR).

I am responsible for at minimum ensuring that:

a) the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released;
b) the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date;
c) the post-market surveillance obligations are complied with in accordance with EU MDR Article 10(10);
d) the reporting obligations referred to in EU MDR Articles 87 to 91 are fulfilled;
e) in the case of investigational devices, the statement referred to in EU MDR Section 4.1 of Chapter II of Annex XV is issued.

I attest that I maintain the requisite expertise in the field of medical devices demonstrated through a degree and certificate, awarded on completion of a university degree and course of study recognised as equivalent by the Member State concerned, in a scientific discipline and have over four years of professional experience in regulatory affairs and in quality management systems relating to medical devices.

Gwendolyn Pinto
Director, RA & QA
Exact Imaging Inc.
E. gpinto@exactimaging.com
W. www.exactimaging.com