

Manufacturer's Name: Hologic, Inc.
 Manufacturer's Address: 36 Apple Ridge Road
 Danbury, CT 06810 USA

Type of Equipment: X-Ray Mammography
 Stereotactic Biopsy Systems

Model Designation: Selenia® Dimensions® Digital Mammography System
 Affirm™ Breast Biopsy Guidance System

The following exemptions defined in Directive 2011/65/EU are applied to the Selenia Dimensions Digital Mammography System and the Affirm Breast Biopsy Guidance System.

Annex	Exemption
IV-23	Lead as an alloying element for bearings and wear surfaces in medical equipment exposed to ionizing radiation.
III -7(c)-I	Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, for example, piezoelectronic devices, or in a glass or ceramic matrix compound
III- 6(a)	Lead as an alloying element in steel for machining purposes and in galvanized steel containing up to 0.35% lead by weight
III- 6(c)	Copper alloy containing up to 4% lead by weight
IV-5	Lead in shielding for ionizing radiation