

RoHS Declaration

Dimensions/3Dimensions Mammography System
Affirm Breast Biopsy Guidance System

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® Mammography System
3Dimensions™ Mammography System
Affirm® Breast Biopsy Guidance System

The following exemptions defined in Directive 2011/65/EU (RoHS II) and 2015/863/EU are applied to the Selenia Dimensions/3Dimensions 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 |

See the following page for the RoHS Declaration table for these systems.

RoHS Declaration Table for:

Selenia® Dimensions® Mammography System
3Dimensions™ Mammography System
Affirm® Breast Biopsy Guidance System

| Component | Lead (Pb) < 0.1% | Mercury (Hg) < 0.1% | Cadmium (Cd) < 0.01% | Hexavalent Chromium (Cr(vi)) < 0.1% | Poly-brominated Biphenyls (PBB) < 0.1% | Poly-brominated Diphenyl Ether (PBDE) < 0.1% |
|-------------|---------------------|------------------------|-------------------------|--|---|---|
| Gantry | O | O | O | O | O | O |
| Generator | O | O | O | O | O | O |
| Tube | X | O | O | O | O | O |
| Collimator | X | O | O | O | O | O |
| Detector | X | O | O | O | O | O |
| UPS | O | O | O | O | O | O |
| Workstation | O | O | O | O | O | O |
| Accessory | O | O | O | O | O | O |

O: Indicates that the hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement of GB/T 26572.*

X: Indicates that the hazardous substance contained in at least one of the homogeneous materials used for this part is above the limit requirement of GB/T 26572.*

X: The Tube, Collimator, and Detector use lead for shielding of ionizing radiation intended for the protection of the patient and technical personnel.

*"Requirements on concentration limits for certain restricted substances in electrical and electronic products" as stated in SJ/T 11364 (2014) *Marking Requirements for Restricted Use of Hazardous Substances in Electronic and Electrical Products*, issued by the Ministry of Industry and Information Technology of the People's Republic of China.