Date: 13-October-2019 Version: 4.0
Title: UAE RoHS – Implementing Guidelines for **Medical Devices**
Reference(s): --
Remarks: This document provides guiding principles for the implementation of the UAE RoHS – Restriction of Hazardous Substances – Decision No. 10 of 2017.

## I. Important Updates

- **Required Document: Declaration of Compliance (v4.0)**
- **The Manufacturer in accordance with the procedures of IEC 63000:2016 (or EN 50581:2012) shall assess products covered by the issued Declaration of Compliance.**
- **One Declaration of Compliance shall be issued for model/s (under a single product type) – maximum count that can be covered under one Certificate of Conformity depending on which type of Certification selected (ECAS or EQM).**
- **The regulation shall cover B2B (Business to Business) and B2C (Business to Consumer) products.**

## II. Scope

This Implementing Guideline is strictly applicable only for medical devices covered under Category 8 of UAE Regulation No. 10 of 2017 – Restriction of the Use of Hazardous Substances in Electrical and Electronic Equipment (EEE).

**Table 1 (*category 8 only*)**

| Sr. | Category | Types |
|---|---|---|
| 8 | Medical devices (with exception of all implanted and infected products) | • Radiotherapy equipment<br>• Cardiology equipment<br>• Dialysis equipment<br>• Pulmonary ventilators<br>• Nuclear medicine equipment<br>• Laboratory equipment for in-vitro diagnosis<br>• Analyzers<br>• Freezers<br>• Fertilization tests<br>• Other appliances for detecting, preventing, monitoring, treating, alleviating illness, injury, or disability |

## III. Exemptions

| Sr. | Category | Description/Definition |
|---|---|---|
| 1 | Military / Security | Equipment which is necessary for the protection of the essential interests of the security of the country, including arms, munitions and war material intended for specifically military purposes. |
| 2 | Outer Space | Equipment designed to be sent into space. |
| 3 | Special Design | Equipment which is specifically designed, and is to be installed, as part of another type of equipment that is |

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| | | excluded or does not fall within the scope of this Regulation, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment. |
| 4 | Large-scale stationary industrial tools | Large-scale assembly of machines, equipment, and/or components, functioning together for a specific application, permanently installed and de-installed by professionals at a given place, and used and maintained by professionals in an industrial manufacturing facility or research and development facility. |
| 5 | Large-scale fixed installations | Large-scale combination of several types of apparatus and, where applicable, other devices, which are assembled and installed by professionals, intended to be used permanently in a pre-defined and dedicated location, and de-installed by professionals. |
| 6 | Non-type approved means of transport | Means of transport for persons or goods, excluding electric two-wheel vehicles which are not type-approved. |
| 7 | Non-road mobile machinery made available exclusively for professional use | Machinery, with an on-board power source, the operation of which requires either mobility or continuous or semi-continuous movement between a succession of fixed working locations while working, and is made available exclusively for professional use. |
| 8 | Active implantable medical devices | Any medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure. |
| 9 | Professional photovoltaic panels | Photovoltaic panels intended to be used in a system that is designed, assembled and installed by professionals for permanent use at a defined location to produce energy from solar light for public, commercial, industrial and residential applications. |
| 10 | R&D Equipment for B2B basis | Equipment specifically designed solely for the purposes of research and development only made available on a business-to-business (B2B) basis, |
| 11 | Products for general lighting | Equipment currently covered under the UAE Cabinet Decision No. 34 of 2013. |

## IV. Notification of Exemptions

Notification for exemptions or cancellation of such exemption shall be submitted to ESMA* by a manufacturer, the authorized representative of a manufacturer and shall include at least the following:

1. Name, address and contact details of the applicant;
2. Information on the material or component and the specific uses of the substance in the material and component for which exemption, or its revocation is requested and its particular characteristics;
3. Evidence of granted exemption in reference to the procedures and requirements detailed in EU RoHS Directive 2011/65/EU.

**Notification of exemptions shall be submitted (via email) to Eng. Hana AlKhokardi (hana@esma.gov.ae), Eng. Marco Intalan (marco@esma.gov.ae) and copy to Dr. Yousef Al Saadi (yousef.a@esma.gov.ae) and Eng. Ahlam Al Marzouqi (ahlam@esma.gov.ae).*

## V. Restricted Substances

The UAE regulation intention is to control or limit presence of the following hazardous substances on electrical and electronic devices:

1. Lead (Pb)
2. Mercury (Hg)
3. Cadmium (Cd)
4. Hexavalent chromium (Vi)
5. Polybrominated biphenyls (PBB)
6. Polybrominated biphenyl ethers (PBDE)
7. Bis (2-ethyhexyl) phthalate (DEHP) – *to be regulated by January 1, 2022*
8. Butyl benzyl phthalate (BBP) – *to be regulated by January 1, 2022*
9. Dibutyl phthalate (DBP) – *to be regulated by January 1, 2022*
10. Diisobutyl phthalate (DIBP) – *to be regulated by January 1, 2022*

## VI. Applicable Standards

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| IEC/TR 62476:2010 | Guidance for the evaluation of products with respect to substance-use restrictions in electrical and electronic products |
| IEC 63000:2016 | Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances |
| IEC 62321:2008 | Electrotechnical products - Determination of levels of six regulated substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers) |
| IEC 62321-1:2013 | Determination of certain substances in electrotechnical products - Part 1: Introduction and overview |
| IEC 62321-2:2013 | Determination of certain substances in electrotechnical products - Part 2: Disassembly, disjointment and mechanical sample preparation |
| IEC 62321-3-1:2013 | Determination of certain susbtances in electrotechnical products - Part 3-1: Screening - Lead, mercury, cadmium, total chromium and total bromin by X-ray fluorescence spectrometry |
| IEC 62321-3-2:2013 | Determination of certain substances in electrotechnical products - Part 3-2: Screening - Total bromine in polymers and electronics by Combustion - Ion Chromatography |
| IEC 62321-4:2017 | Determination of certain substances in electrotechnical products - Part 4: Mercury in polymers, metals and electronics by CV-AAS, CV-AFS, ICP-OES and ICP-MS |

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| IEC 62321-5:2013 | Determination of certain substances in electrotechnical products - Part 5: Cadmium, lead and chromium in polymers and electronics and cadmium and lead in metals by AAS, AFS, ICP-OES and ICP-MS |
| IEC 62321-6:2015 | Determination of certain substances in electrotechnical products - Part 6: Polybrominated biphenyls and polybrominated diphenyl ethers in polymers by gas chromatography - mass spectrometry (GC-MS) |
| IEC 62321-7-1:2015 | Determination of certain substances in electrotechnical products - Part 7-1: Hexavalent chromium - Presence of hexavalent chromium (Cr(VI)) in colourless and coloured corrosion-protected coatings on metals by the colorimetric method |
| IEC 62321-7-2:2017 | Determination of certain substances in electrotechnical products - Part 7-2: Hexavalent chromium - Determination of hexavalent chromium (Cr(VI)) in polymers and electronics by the colorimetric method |
| IEC 62321-8:2017 | Determination of certain substance in electrotechnical products - Part 8: Phthalates in polymers by gas chromatography-mass spectrometry (GC-MS), gas chromatography-mass spectrometry using a pyrolyzer/thermal desorption accessory (Py/TD-GC-MS) |
| IEC 62474:2012 | Material declaration for products of and for the electrotechnical industry |
| IEC TR 62474-1:2015 | Material declaration for products of and for the electrotechnical industry - Part 1: Guidance for the implementation of IEC 62474 |