VERŻJONI ELETTRONIKA



*Suppliment tal-Gazzetta tal-Gvern ta' Malta Nru. 19,685, 25 ta' Novembru, 2016*
*Taqsima B*

**L.N. 391 of 2016**

# PRODUCT SAFETY ACT (CAP. 427)

## Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2016

IN exercise of the powers conferred by articles 38 to 40 of the Product Safety Act, Minister for Social Dialogue, Consumer Affairs and Civil Liberties, on the advice of the Malta Competition and Consumer Affairs Authority, has made the following regulations:-

Citation.

**1.** The title of these regulations is the Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2016, and these regulations shall be read and construed as one with the Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment Regulations, hereinafter referred to as "the principal regulations".

S.L.427.57

Implementation.

**2.** (1) These regulations implement the following European Union legislation:

(a) Commission Delegated Directive (EU) 2016/585 of 12 Feb 2016 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices or electron microscopes;

(b) Commission Delegated Directive (EU) 2016/1028 of 19 April 2016 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders of electrical connections to temperature measurement sensors in certain devices; and

(c) Commission Delegated Directive (EU) 2016/1029 of 19 April 2016 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium anodes in Hersch cells for certain oxygen sensors used in industrial monitoring and control instruments.

(2) These regulations shall apply to equipment falling under the scope of the principal regulations.

(3) Regulation 3 shall apply as from the 6th November 2017.

Amends Schedule IV to the principal regulations.

**3.** Schedule IV to the principal regulations shall be amended as follows:

(a) item 26 thereof shall be substituted by the following:

"26. Lead in the following applications that are used durably at a temperature below – 20 °C under normal operating and storage conditions:

(a) solders on printed circuit boards;

(b) termination coatings of electrical and electronic components and coatings of printed circuit boards;

(c) solders for connecting wires and cables;

(d) solders connecting transducers and sensors. Lead in solders of electrical connections to temperature measurement sensors in devices which are designed to be used periodically at temperatures below – 150 °C. These exemptions expire on 30 June 2021.";

(b) item 31 thereof shall be substituted by the following:

"31. Lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, or electron microscopes and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer. Expires on 21 July 2021 for the use in medical devices other than in vitro diagnostic medical device, expires on 21 July 2023 for the use in in vitro diagnostic medical devices and expires on 21 July 2024 for the use in electron microscopes and their accessories.' Cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic."; and

(c) immediately after item 42 thereof there shall be added the following new item:

"43. Cadmium anodes in Hersch cells for oxygen sensors used in industrial monitoring and control instruments, where sensitivity below 10ppm is required. Expires on 15 July 2023.".

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