

January 28, 2021

EU extends the exemptions date beyond July 2021 - RoHS Directive 2011/65/EU Annex IV 1b Lead anodes in electrochemical oxygen sensors

RoHS Directive 2011/65/EU was published in 2011 by the EU, which is known as RoHS-Recast or RoHS 2. RoHS 2 includes a CE-marking directive, with RoHS compliance now being required for CE marking of products. RoHS 2, and the subsequent RoHS 3, included additional Categories that included exemptions from required compliance dates. The information below can be found at www.rohsguide.com

Lead Category Exemption Deadlines

July 21, 2021: All categories except for Category 8 in-vitro diagnostic medical devices, Category 9 industrial monitoring & control instruments, Category 11 products

July 21, 2023: Category 8 in-vitro diagnostic medical devices (IVDs)

July 21, 2024: Category 9 industrial monitoring & control instruments; Category 11 products

The exemption that allowed the extended use of lead anodes in electrochemical oxygen sensors used in various medical products was set to expire on July 21, 2021. The European Commission (EC) does have a formal process that allows for the submittal of an application to request the extension of an exemption date.

On January 15, 2020 an Exemption Request was filed with the European Commission to extend the compliance date for Annex IV, 1b lead anodes in electrochemical oxygen sensors. This request has been accepted by the European Commission and identified as "Valid – Request for Renewal". The exemption date, based on the initial review of this exemption request, **extends the exemption date beyond the July 21, 2021 date.** The new exemption deadline date will be established once the review is completed. The European Commission provides the following guidance on the review process; "Considering the very large amount of renewal applications received, the expected timeframe for the Commission to take a decision on a RoHS exemption application is currently approximately 24 months from the application date."

The information related to this exemption request can be found on the following website: European Commission; Restriction of Hazardous Substances in Electrical and Electronic Equipment; Adaptation to technical and scientific progress of the RoHS 2 Annexes III and IV.

https://ec.europa.eu/environment/waste/rohs_eee/adaptation_en.htm

The tracking of exemption request applications can be found at the following website: Directive 2011/65/EU (RoHS2); Validity and rolling plan, version 17/04/2020. The Annex IV 1b exemption request can be found in row 133 https://ec.europa.eu/environment/waste/rohs_eee/pdf/Copy%20of%20Exemptions%20list%20-%20validity%20and%20rolling%20plan_17Apr%2020_public.xlsx

Sincerely,



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