Client Alert

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RoHS-2 Directive Will Soon Apply to Medical Devices: What Medical Device Companies Should Do

Directive 2011/65/EU (the "RoHS-2 Directive"), which was adopted in 2011 and replaced the original 2003 "RoHS-1" Directive, imposes chemical restrictions, conformity assessment and CE- marking requirements, and post-marketing surveillance obligations on manufacturers, importers and distributors of electrical and electronic equipment ("EEE"). While the RoHS-1 Directive did not apply to medical devices, the RoHS-2 Directive will apply to electrical and electronic medical devices "placed on the market from 22 July 2014" onwards. This date is 22 July 2016 in the case of in vitro diagnostic medical devices.

"Placing on the Market"

This implies that manufacturers of electronic and electrical medical devices intended for the EU market have to assess and document whether their products comply with the RoHS-2 Directive's chemical restrictions. "Non-compliant" devices, however, may continue to be placed on the market until 21 July 2014. Under RoHS-2, placing on the market is defined as "any supply of an EEE for (…) distribution, consumption or use (…) in the course of a commercial activity, whether in return for payment or free of charge, on the Union market for the first time." A product is placed on the market when it is made available "for the first time," thus used products imported for the first time in the EU are considered to be placed on the market at the time of their import.

No further definition of the term, criteria or guidance are provided in the RoHS-2 Directive. The European Commission, however, recently adopted a revised 'Blue Guide' on the Implementation of EU Product Rules (the "Blue Guide") that provides further guidance relevant to the RoHS-2 Directive. According to the 2014 Blue Guide, placing on the market "requires an offer or an agreement (written or verbal) between two or more legal or natural persons for the transfer of ownership, possession or any other property right concerning the product in question. This transfer could be for payment or free of charge. It does not require the physical handover of the product."

Even if the Blue Book guidance is applied, not all issues are resolved. Determining when a transfer occurs for each product category may not be easy. For example, a medical device in transit to the EU but not yet imported, may or may not be placed on the market.

Ensuring RoHS-2 Compliance

Manufacturers and importers must ensure continuing compliance with the RoHS-2 Directive, including market surveillance obligations and through procedures for series production to remain in conformity. In some cases, compliance with all chemical restrictions may not be possible, and a company may have to apply for an exemption. This process may take several months or longer.

To ensure compliance on an on-going basis, manufacturers and importers also have to monitor changes to the list of substances restricted under the RoHS-2 Directive. The RoHS-2 Directive currently restricts the following substances: lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls and polybrominated diphenyl ethers. The European Commission, following a recommendation of the Austrian Environmental Agency, is currently considering adding the brominated flame retardant HBCDD and the

phthalates DEHP, BBP and DBP to the list. Other substances that have been prioritized for inclusion at a later stage include PVC, tris(2-chloroethyl)phosphate, 2,3-dibromo-1-propanol and dibromoneopentyl-glycol.

Suppliers of used or reconditioned medical devices must be mindful that non-compliant products initially lawfully placed on the market before 22 July 2014 may no longer be sold or otherwise made available after 22 July 2019. A European Commission study, however, concluded that the 2019 deadline would have a significant negative environmental, economic and social impact without producing significant benefits in respect of medical devices. As a consequence, the European Commission might propose a legislative amendment excluding the application of this deadline to medical devices.

How Hunton & Williams Can Help

Hunton & Williams has experience assisting clients with all areas of law that affect the medical devices industry. We advise clients on a wide range of regulatory matters, including compliance management, liability assessment, inspections and enforcement, and legal remedies. Working closely with our clients and with regulatory and technical experts, we ensure that our clients' interests are effectively protected.

Hunton & Williams is a global law firm with a strong focus on regulatory law and with qualified and experienced lawyers on both sides of the Atlantic, in its offices in Brussels, Raleigh, and Washington D.C.

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