A Breakdown of the Top 10 Critical RoHS2 Requirements

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Medical device CE-mark compliance deadline coming fast.

While legal enforcement dates for RoHS2 compliance is July 22, 2014, Northwire, a leading OEM, is alerting their valued customers in medical equipment manufacturing of the critical details to make certain they comply with CE-mark.

Originally published in July 2011, the Recast RoHS Directive dictates that all medical devices, electrical and electronic OEMs comply with new standards. Failure to comply with RoHS2 can prohibit CE-mark approval and result in product restrictions. To ensure your success, NWI, a leading manufacturer of custom medical cable, medical wire and medical assemblies navigates the complexities of RoHS2 to bring you the Top 10 key requirements.

No. 10: Time Is of the Essence
Importers' requests for product compliance typically start six months before the legal deadline. You should have adopted the directive by June 2013 to ensure supply chain and inventory compliance by January 2014.

No. 9: CE 'Marks the Spot'
To ensure CE-mark compliance, you must adjust your target to meet compliance with the RoHS2 Directive, because you cannot CE-mark products without it.

No. 8: It's the Law
Effective January 2, 2013, the EU adopted RoHS2 into National Law making it legally enforceable by the "surveillance authority."

No. 7: Burden of Proof
Not limited to a Declaration of Conformity, you are responsible for validation on various forms of technical documentation.

No. 6: Substance Abusers Beware
Six hazardous and restricted substances are clearly defined as lead, mercury, cadmium, hexavalent chromium polybrominated biphenyls, and polybrominated diphenyl ethers.

No. 5: Not Over Yet
…product categories including household appliances; equipment for IT, communications, lighting, and consumer; electrical and electronic tools; equipment for toys, leisure, and sports; and automatic dispensers all require RoHS2 Directive compliance as of January 2, 2013.

No. 4: More to Come
Mark your calendars: formerly excluded categories require future compliance, including monitoring and control instruments; in-vitro diagnostic medical devices; industrial monitoring and control instruments; all other electrical and electronic equipment not covered; and active implantable medical devices reviewed for inclusion.

No. 3: Look Who's Taking Responsibility
"Economic Operators" are the responsible party to ensure CE-mark compliance; they are comprised of the manufacturer, authorized representative, importer, and distributer.

No. 2: C-O-M-P-L-I-A-N-C-E
While Articles 7 through 10 outline specific responsibilities of each party in the supply chain, rely on Northwire's in-house consumer testing technology to validate compliance to RoHS2 and other requirements.

No. 1: Get Ahead of the Competition
With a faster, less expensive go-to-market strategy, you have a decisive advantage over the competition.

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