ROHS REQUIREMENTS ON PHTHALATES FOR MEDICAL DEVICES AND MONITORING & CONTROL INSTRUMENTS

RoHS Directive (2011/65/EU) is the restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE). 11 categories of EEEs are covered by this Directive.

On June 4, 2015, the EU published Directive (EU) 2015/863 in its Official Journal, amending Annex II to Directive 2011/65/EU (RoHS Directive) by adding four phthalates (DEHP, BBP, DBP, DIBP) to the restricted substances list. Thus, the number of restricted substances in the list under RoHS Directive increased from 6 (Lead, Cadmium, Mercury, Hexavalent chromium, PBB, PBDE) to 10 substances.

The corresponding transition period was given to the implementation of the requirements of the four phthalates.

The maximum concentration limits (by weight) in homogeneous materials of the four phthalates are 0.1% (1000 mg/kg), and the effective dates are shown below:

PRODUCT CATEGORY	EFFECTIVE DATE
EEEs excluding medical devices and monitoring and control instruments	july 22, 2019
Medical Devices and Monitoring and Control Instruments	July 22, 2021

DEHP, BBP, DBP and DIBP are primarily used as plasticizers to soften plastics. They have been restricted since 22 July 2019 for all electrical and electronic equipment apart from Category 8 (medical devices) and Category 9 (monitoring and control equipment). The transition period for Category 8 and 9 EEEs ends on 22 July 2021. Thus, the restriction applies to all EEE thereafter.

As the effective date draws closer, SGS recommends relevant manufacturers of medical devices and monitoring and control instruments to investigate the materials used in your products in time to ensure compliance with the RoHS Directive. As a retailer importing electrical and electronic products into the European Union, it is the stakeholders' responsibility to prove that your products comply with relevant RoHS testing legislation and guidelines.

Please contact our Customer Service Team for more information!

With a proven track record in product safety certification, SGS' global network of RoHS accredited labs and specialists are the ideal partner to verify your compliance to RoHS.