

Restriction of Hazardous Substances (2011/65/EU | (EU) 2015/863 RoHS) & WEEE Declaration All Electrical and Electronic Equipment

Regarding QINSTRUMENTS activities with respect to the Restriction of Hazardous Substances in Electrical and

Electronic Equipment (RoHS), please be advised of the following:

Executive Summary

Each manufacturer of laboratory instruments and medical devices bear a heavy responsibility for its products. These have to comply with legal requirements and EU regulations.

The RoHS Directive 2011/65/EU (RoHS 2) became effective on 3 January 2013. RoHS 2 deals with the same hazardous substances and the same maximum concentration limits as Directive 2002/95/EC (RoHS 1). Therefore, all products meeting the substance restrictions of RoHS 1 remain compliant to the substance restrictions of RoHS 2. The scope of RoHS 2 expanded to phase in the previously excluded categories of medical devices and monitoring & control instruments, as well as certain cables.

In addition, RoHS 2, for finished EEE (*EEE = Electrical and Electronic Equipment*), requires the use of the CE mark to demonstrate compliance with the Directive. The commentary below provides more detail related to QINSTRUMENTS approach to ensure compliance to RoHS 2.

The amendment (EU) 2015/863 adds four additional substances to Annex II of 2011/65/EU, especially known under **RoHS 3**. The additional four substances restriction and evidence requirements shall be applied for products placed on the market on or after 22 July 2019.

To reduce the environmental impact of waste electrical and electronic equipment (WEEE), the European Parliament and the Council of the European Union have implemented Directive 2002/96/EC. The directive mandates that producers of the electrical and electronic equipment provide their customers information about proper disposal.

Awareness and Focus

QINSTRUMENTS is fully aware of RoHS and has continued to monitor the developing implementation guidelines and national transpositions.

Substance Restrictions

RoHS 1: lead (0.1%), mercury (0.1%), cadmium (0.01%), hexavalent chromium (0.1%), polybrominated biphenyls [PBB] (0.1%), polybrominated diphenyl ethers [PBDE] (0.1%).

RoHS 2 deals with the same six hazardous substances and the same maximum concentration limits as RoHS1.

Amendment (EU) 2015/863: Bis(2-Ethylhexyl) phthalate [DEHP] (0,1%), Benzyl butyl phthalate [BBP] (0,1%), Dibutyl phthalate [DBP] (0,1%), Diisobutyl phthalate [DIBP] (0,1%).

CE Marking

In contrast to RoHS 1, RoHS 2 is a CE marking Directive, and requires, for finished EEE, the use of the CE mark on the product to show compliance. The responsibility for affixing the CE mark resides with the manufacturer. For finished EEE where QINSTRUMENTS is the legal manufacturer, QINSTRUMENTS will affix the CE mark.

For finished EEE that QINSTRUMENTS produces for OEMs, the CE mark can, similar to other customer specifications, be affixed by QINSTRUMENTS on the customers behalf without QINSTRUMENTS assuming the OEMs' (manufacturers') responsibility (see section on technical documentation).

Please be advised that CE marking for RoHS 2 only applies to finished EEE in scope of RoHS 2.

Declaration of Conformity (DoC) and Technical Documentation

In addition to placing the CE mark on all finished EEE in scope of RoHS 2, all CE marked EEE will require a Declaration of Conformity (DoC) and associated technical documentation. The responsibility for this DoC and documentation resides with the manufacturer. For finished EEE where QINSTRUMENTS is the legal manufacturer, QINSTRUMENTS will provide the DoC and prepare technical documentation per Harmonised European Standard EN IEC 63000:2018 (German version DIN EN IEC 63000:2019). For finished EEE that QINSTRUMENTS produces for OEMs, it is only the OEM that can fulfil the obligations to provide the required documentation under its own name.

WEEE - Registration Number DE 50498740

We have registered with the Electrical and Electronic Equipment Waste Register (EAR) for articles in accordance with §6 Abs.2 ElektroG.

Disposal of Electronic Equipment

The various national implementations of the Directive suggest regulations governing the proper disposal of equipment will vary.

For electrical devices, which were delivered before the 08/13/2005, the last user is responsible for proper disposal. A return of devices which were delivered after 8/13/2005 with consumer brands QINSTRUMENTS and BioShake to municipal collection points is no longer permitted. With the disposal of the equipment delivered after 8/13/2005 QINSTRUMENTS have engaged the certified waste disposal firm "Municipal Service Jena" (operating through the city of Jena/Germany).

The WEEE symbol and description apply to all QINSTRUMENTS electrical and electronic products placed on the European Market after August 13, 2005.



Do not dispose of this product as unsorted municipal waste. Follow local municipal waste ordinances for proper disposal provisions to reduce the environmental impact of waste electrical and electronic equipment (WEEE).

European Union customers: Call our QINSTRUMENTS Customer Service office for complimentary equipment pick-up and recycling.

See <http://www.QInstruments.com> for more information.

Beginning August 13, 2005, QInstruments affixed the wheeled bin symbol with a bar to appropriate products. The bar indicates that the product was placed on the market after August 13, 2005.

Conclusion

QINSTRUMENTS will continue closely monitoring legislative and guidance developments and update this letter as appropriate.

Reporting and notification obligations pursuant to Section 18 of the Electrical and Electronic Equipment Act / Section 2 of the Act on the Implementation of the Waste Framework Directive:

<https://www.take-e-way.com/services/weee-elektrog/reporting-and-information-obligations/>

Declaration was at first applied: 2009

Released by: Olaf Simmat
Position: Managing Director

Date of issue: December 1st, 2023
Place of issue: Jena, Germany