

EU RoHS Compliance of INTEGRA Biosciences Instruments

EU Directive 2011/65, amendments and delegated directives

The long list of amendments and delegated directives to the EU **R**estrictions **o**f **H**azardous **S**ubstances (RoHS) directive 2011/65 EU is not referenced in full length in INTEGRA's conformity declarations for simplicity reasons. In order to assist customers, this document explicitly lists all amendments and delegated directives which are covered by INTEGRA's 2011/65 conformity statements as of March 31st 2021. This list is regularly updated by the EU. The most up to date version can be found here: https://ec.europa.eu/environment/topics/waste-and-recycling/rohs-directive_en

1 Law

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Directive (EU) 2017/2102 of the European Parliament and of the Council of 15 November 2017 amending Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment

2 Restricted substances (Annex II)

Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances

3 Exemptions (Annex III and IV)

Commission Delegated Directive (EU) 2020/360 of 17 December 2019 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in platinized platinum electrodes used for certain conductivity measurements

Commission Delegated Directive (EU) 2020/361 of 17 December 2019 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators

Commission Delegated Directive (EU) 2020/364 of 17 December 2019 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of cadmium in certain radiation tolerant video camera tubes

Commission Delegated Directive (EU) 2020/365 of 17 December 2019 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders and termination finishes used in certain hand-held combustion engines

Commission Delegated Directive (EU) 2020/366 of 17 December 2019 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as a thermal stabiliser in polyvinyl chloride used in certain in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases

Commission Delegated Directive (EU) 2019/1845 of 8 August 2019 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for bis(2-ethylhexyl) phthalate (DEHP) in certain rubber components used in engine systems

Commission Delegated Directive (EU) 2019/1846 of 8 August 2019 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders used in certain combustion engines

Commission Delegated Directive (EU) 2019/169 of 16 November 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in dielectric ceramic in certain capacitors

Commission Delegated Directive (EU) 2019/170 of 16 November 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in PZT based dielectric ceramic materials for certain capacitors

Commission Delegated Directive (EU) 2019/171 of 16 November 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium and its compounds in electrical contacts

Commission Delegated Directive (EU) 2019/172 of 16 November 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages

Commission Delegated Directive (EU) 2019/173 of 16 November 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead and cadmium in printing inks for the application of enamels on glasses

Commission Delegated Directive (EU) 2019/174 of 16 November 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead bound in crystal glass as defined in Directive 69/493/EEC

Commission Delegated Directive (EU) 2019/175 of 16 November 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead oxide in seal frit used for making window assemblies for certain laser tubes

Commission Delegated Directive (EU) 2019/176 of 16 November 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in the plating layer of certain diodes

Commission Delegated Directive (EU) 2019/177 of 16 November 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as activator in the fluorescent powder of discharge lamps containing phosphors

Commission Delegated Directive (EU) 2019/178 of 16 November 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in bearings and bushes applied in certain non-road professional use equipment

Commission Delegated Directive (EU) 2018/739 of 1 March 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as an alloying element in steel

Commission Delegated Directive (EU) 2018/740 of 1 March 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as an alloying element in aluminium

Commission Delegated Directive (EU) 2018/741 of 1 March 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as an alloying element in copper

Commission Delegated Directive (EU) 2018/742 of 1 March 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in high melting temperature solders

Commission Delegated Directive (EU) 2018/736 of 27 February 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for certain electrical and electronic components containing lead in glass or ceramic

Commission Delegated Directive (EU) 2018/737 of 27 February 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors

Commission Delegated Directive (EU) 2018/738 of 27 February 2018 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in cermet-based trimmer potentiometer elements

Commission Delegated Directive (EU) 2017/1975 of 7 August 2017 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium in colour converting light-emitting diodes (LEDs) for use in display systems

Commission Delegated Directive (EU) 2017/1009 of 13 March 2017 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium and lead in filter glasses and glasses used for reflectance standards

Commission Delegated Directive (EU) 2017/1010 of 13 March 2017 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in bearing shells and bushes for certain refrigerant-containing compressors

Commission Delegated Directive (EU) 2017/1011 of 15 March 2017 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in white glasses used for optical applications

Commission Delegated Directive (EU) 2016/1028 of 19 April 2016 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders of electrical connections to temperature measurement sensors in certain devices

Commission Delegated Directive (EU) 2016/1029 of 19 April 2016 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium anodes in Hersch cells for certain oxygen sensors used in industrial monitoring and control instruments

Commission Delegated Directive (EU) 2016/585 of 12 February 2016 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as

regards an exemption for lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices or electron microscopes

Commission Delegated Directive (EU) 2015/573 of 30 January 2015 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in polyvinyl chloride sensors in in-vitro diagnostic medical devices

Commission Delegated Directive (EU) 2015/574 of 30 January 2015 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for mercury in intravascular ultrasound imaging systems

Commission Delegated Directive 2014/69/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in dielectric ceramic in capacitors for a rated voltage of less than 125 V AC or 250 V DC for industrial monitoring and control instruments

Commission Delegated Directive 2014/70/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in micro-channel plates (MCPs)

Commission Delegated Directive 2014/71/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solder in one interface of large area stacked die elements

Commission Delegated Directive 2014/72/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems

Commission Delegated Directive 2014/73/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in platinized platinum electrodes used for conductivity measurements

Commission Delegated Directive 2014/74/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead used in other than C-press compliant pin connector systems for industrial monitoring and control instruments

Commission Delegated Directive 2014/75/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for mercury in cold cathode fluorescent lamps (CCFLs) for back-lighting liquid crystal displays, not exceeding 5 mg per lamp, used in industrial monitoring and control instruments placed on the market before 22 July 2017

Commission Delegated Directive 2014/76/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for Mercury in hand crafted luminous discharge tubes (HLDTs) used for signs, decorative or architectural and specialist lighting and light-artwork

Commission Delegated Directive 2014/1/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as an alloying element for bearings and wear surfaces in medical equipment exposed to ionising radiation

Commission Delegated Directive 2014/2/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as

regards an exemption for cadmium in phosphor coatings in image intensifiers for X-ray images until 31 December 2019 and in spare parts for X-ray systems placed on the EU market before 1 January 2020

Commission Delegated Directive 2014/3/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead acetate marker for use in stereotactic head frames for use with CT (Computed Tomography) and MRI and in positioning systems for gamma beam and particle therapy equipment

Commission Delegated Directive 2014/4/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead enabling vacuum tight connections between aluminium and steel in X-ray image intensifiers

Commission Delegated Directive 2014/5/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders on printed circuit boards, termination coatings of electrical and electronic components and coatings of printed circuit boards, solders for connecting wires and cables, solders connecting transducers and sensors that are used durably at a temperature below – 20 °C under normal operating and storage conditions

Commission Delegated Directive 2014/6/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in the surface coatings of pin connector systems requiring nonmagnetic connectors which are used durably at a temperature below – 20 °C under normal operating and storage conditions

Commission Delegated Directive 2014/7/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors which are used (a) in magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere, or (b) in magnetic fields within 1 m distance from the external surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy

Commission Delegated Directive 2014/8/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders for mounting cadmium telluride and cadmium zinc telluride digital array detectors to printed circuit boards

Commission Delegated Directive 2014/9/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead and cadmium in metallic bonds creating superconducting magnetic circuits in MRI, SQUID, NMR (Nuclear Magnetic Resonance) or FTMS (Fourier Transform Mass Spectrometer) detectors

Commission Delegated Directive 2014/10/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in alloys, as a superconductor or thermal conductor, used in cryo-cooler cold heads and/or in cryo-cooled cold probes and/or in cryo-cooled equipotential bonding systems, in medical devices (category 8) and/or in industrial monitoring and control instruments

Commission Delegated Directive 2014/11/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for hexavalent chromium in alkali dispensers used to create photocathodes in X-ray image intensifiers until 31 December 2019 and in spare parts for X-ray systems placed on the EU market before 1 January 2020

Commission Delegated Directive 2014/12/EU of 18 October 2013 amending, for the purposes of adapting to

technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders on printed circuit boards of detectors and data acquisition units for Positron Emission Tomographs which are integrated into Magnetic Resonance Imaging equipment

Commission Delegated Directive 2014/13/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders on populated printed circuit boards used in Directive 93/42/EEC class IIa and IIb mobile medical devices other than portable emergency defibrillators

Commission Delegated Directive 2014/14/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for 3,5 mg mercury per lamp in single capped compact fluorescent lamps for general lighting purposes < 30 W with a lifetime equal to or above 20 000 h

Commission Delegated Directive 2014/15/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead, cadmium and hexavalent chromium in reused spare parts, recovered from medical devices placed on the market before 22 July 2014 and used in category 8 equipment placed on the market before 22 July 2021, provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer

Commission Delegated Directive 2014/16/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis lamps containing BSP (BaSi2O5:Pb) phosphors

Commission Delegated Directive 2012/50/EU of 10 October 2012 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for applications containing lead

Commission Delegated Directive 2012/51/EU of 10 October 2012 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for applications containing cadmium

4 Signature

Zizers, 31 March 2021



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