SAFEGUARDS
CONSUMER GOODS AND RETAIL

ELECTRICAL & ELECTRONICS

NO. 205/13 NOVEMBER 2013

EUROPEAN PARLIAMENT BANS HAZARDOUS CHEMICALS IN MEDICAL DEVICES

On 22 October 2013 the European Parliament (EP) voted favorably for the European Commission's proposal on Medical Devices that includes a ban on hazardous chemicals in medical devices.

In accordance with the proposal for a regulation[1] of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 (COM (2012)0542 – C7-0318/2012 – 2012/0266(COD)), the ban applies to chemicals that are CMR[12] 1A and 1 B, or EDCs[13] according to Regulation (EC) No 1272/2008 of CLP[2,14] and other EU laws[15] , and which are contained in medical devices and come into contact with the body of patients or are used to administer, transport or store medicines, body fluids or other substances, including gases in concentrations above 0.1% by weight .

The use of CMR 1A, 1B and EDC should be phased out within 8 years from the entry into force of this Regulation if the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, unless the manufacturer can prove that there are no suitable safer substances or devices without these substances. When the manufacturer can prove that there are no suitable safer substances or devices without these substances, these substances shall be labeled on the device itself and/or on the packaging for each unit as devices containing substances according to ISO 15986.

In spite of the above-mentioned EU proposal there are still many laws related to hazardous substances for medical devices, for examples: EU-RoHS, REACH, POPs and Canada phthalate control act, etc whose overview are given in the table on following page.

[1] Draft European Parliament Legislative Resolution
[2] Regulation (EC) 1272/2008
[3] ECHA - REACH legislation
[4] Directive 2011/65/EU
[5] Proposal for a Council Decision on Persitant Organic Pollutants
[6] ECHA - Biocidal products - Regulation
[7] ECHA - Biocidal products - Product types
[8] DEHP and BPA - Questions & Answers
[9] European Commission - Medical Devices - Other related policies
[10] Candidate List of SVHCs for authorisation
[11] ECHA List of restrictions table
[12] CMR : carcinogenic, mutagenic and toxic to reproduction
[13] EDCs: Endocrine Disrupting Chemicals (EDCs)
[14] CLP: the European Parliament and of the Council of 16 December 2008 on Classification Labeling and Packaging
[15] Directive 67/548/EEC, 1999/45/EC and Regulation 1907/2006

Name of law	Code of law	Requirements		Scope	Date of entry into force
		hazardous substances	thresholds/ actions		
Europe					
RoHS recast[4]	Directive 2011/65/EU	Lead	< 0.1%	electronic medical device excluding active implantable medical devices	22 July 2014
		Cadmium	< 0.01%		
		Mercury	< 0.1%		
		Chromium VI	< 0.1%	electronic IVD	22 July 2016
		PBBs	< 0.1%		
		PBDEs	<0.1%		
REACH	Regulation 1907/2006	SVHC > 0.1% & SVHC[10] > 1t/y	Notifying ECHA	All medical devices	1 June 2007
		SVHC > 0.1%	Providing information of safe use to acceptors or consumers		
		Dangerous substances in Annex 17 [11]	prohibited/ restricted		
POPs[5]	Regulation 850/2004; Regulation 757/2010; Regulation 519/2012	Annex 1	prohibited/ restricted	All medical devices	20 May 2004
		Annex 2	restricted		
Biocidal Product Regulation [6]	Regulation 528/2012	Article is treated with biocidal product containing the approved active substance	Providing the consumers with information about the biocidal treatment of the article that is placed on the market	materials under 22 product types[7]	1 September 2013
Canada					
Phthalate control act[8]	Bill C-307	Phthalates > 0.1%	Notifying Health Canada	All medical devices	when Bill C-307 is passed; the bill is in the third reading.
		Bisphenol A > 0.1%	Notifying Health Canada	The scope is limited to medical device that comes into contact with patient and user's body fluids, tissue and skin	

Besides the laws mentioned in the above table, information about medical device non-chemical EU-laws, such as WEEE, can also be found on European commission's website[9].

SGS is committed to keeping you up to date on the latest regulations and policies concerning the use of hazardous substances in medical devices. Furthermore, through our expertise and global network of chemical labs, SGS can support you in ensuring your products comply with relevant hazardous substances requirements on all relevant markets around the world.

Whether you are in need of hazardous substances testing or other third party verification, certification or inspection services, SGS is an ideal service provider to satisfy all your business's needs.
www.sgs.com/en/Consumer-Goods-Retail/Medical-Devices

FOR ENQUIRIES:

Global Competence Support Centre:
gcsc@sgs.com

TW—Richie Chang
Tel: +886 2 22993279 Ext. 3136 or
richie.chang@sgs.com

Asia – Hong Kong,
Tel: +852 2334 4481,
mktg.hk@sgs.com

Australasia – Perth.
Tel: +61 (0) 3 9790 3418
au.cts@sgs.com

Europe – London – UK.
Tel: +44(0) 203 008 7860
gb.cts.sales@sgs.com

Africa & Middle East – Turkey.
Tel: +90 212 368 40 00
sgs.turkey@sgs.com

Americas – USA.
Tel: +1 973 575 5252
uscts.inquiries@sgs.com

www.sgs.com/cgnr