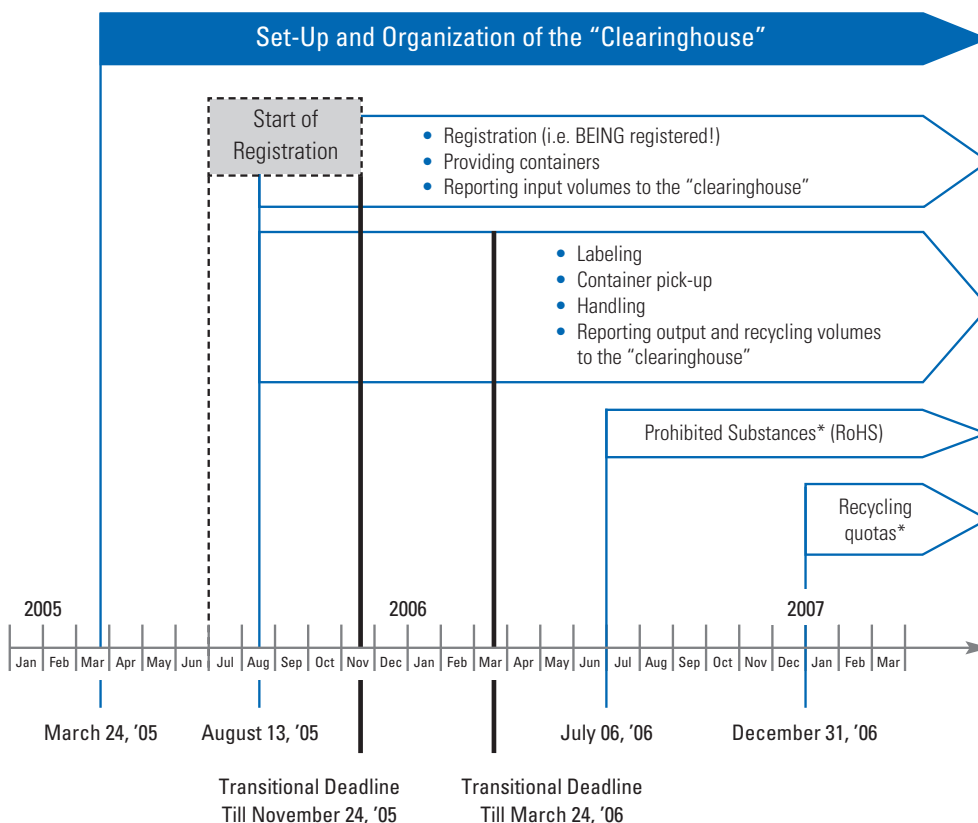


## ElektroG—Deadlines and Obligations for Manufacturers of Medical Products

The following text provides up-to-date information on the implementation of the Electrical and Electronic Equipment Act (Elektro G) for manufacturers of medical products.

The Electrical and Electronic Equipment Act (Elektro G) of March 23, 2005 concerning the marketing, take-back, and environmentally sound disposal of electrical and electronic equipment also obligates the manufacturers of medical equipment to register, label, and collect used medical equipment. Since the German implementation of the European guidelines (WEEE + RoHS) was carried out before almost all other European countries, we present a short summary of the changes:



\*currently, medical products are still excepted

Source: Stiftung-ear

[www.tuev-sued.com/mhs](http://www.tuev-sued.com/mhs)

### Labeling

Starting August 13, 2005, products must be labeled as follows:

- Unique manufacturer's ID
- The crossed-out garbage can symbol
- Limit date for marketing (either using unencrypted text YYYY-MM-DD and/or by bar code under the crossed-out garbage can)



### Registration

By November 23, 2005, all manufacturers must register with the EAR (Elektroaltgeräteregister = WEEE register). Electronic registration is possible at [www.ear-stiftung.de](http://www.ear-stiftung.de).

Details on registration, financial guarantees, disposal chains, and volume reports can be obtained from the EAR. Registration is possible starting in July 2005.

### Reporting Obligations

Starting in November 2005, manufacturers must report the "input volumes" monthly (type and volume of equipment), broken down by private households (B2C) and commercial users

(B2B) to the EAR, or demonstrate the organizational prerequisites for these reports. By March 2006 at the latest, all manufacturers must also report the "output and recycling" volumes.

### Disposal

Starting in March 2006, the take-back system must be operational and be picking up and disposing of the old equipment. For this purpose, disposal service providers may be hired that provide communal collection containers and handle the pick-up and disposal of the devices from B2C. Manufacturers bear the costs for

disposal of equipment from private households. For the take-back of purely commercial equipment from B2B, the manufacturers must implement an appropriate take-back and disposal system for old equipment. Contracts and general terms and conditions of doing business will regulate who bears the costs.

### Prohibited Substances

The material prohibitions, which forbid more than 0.1 weight percent lead, mercury, hexavalent chrome, polybrominated biphenyl (PBB), or polybrominated diphenylether (PBDE) per homogeneous material, or more than 0.01 weight percent cadmium per homogeneous material, currently do not apply to medical products. This exception has been under

examination in a European Commission study since the spring of 2005. Regardless of the results of the study, the availability of components and modules that do not meet the RoHS guidelines will probably be reduced, so that it will be necessary to make changes in design and to adapt production methods.

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