



COCIR PROPOSAL

To amend Annex IC "Minimum requirements for shipment of used EEE" WEEE Directive recast

COCIR represents the Radiological, Electromedical and Healthcare IT Industry in Europe. While COCIR appreciates the European Council and Parliament having addressed other important issues, there are still elements of significant importance that could be improved.

COCIR recommends to Amend Annex IC requirements to facilitate the rightful cross-border shipment of used medical devices.

COCIR proposed amendment 1:

Annex IC, 1b) new

"Paragraph 1 points a) and b) shall not apply to highly technological professional devices, including medical devices, their subsystems or parts of it, when they are sent for repair, refurbishment or reprocessing, to the producer or producer' group or their mandated companies with the intention of reuse.

For the purpose of meeting regulatory vigilance requirements (medical device reporting) under Directive 93/42/EEC or Directive 98/79/EC, paragraph 1 points a) and b) shall not apply to allow necessary shipments".

Rationale: Annex IC, in its current wording, does not permit medical devices manufacturers a successful back-up claim for all of the rightful shipments of used EEE, especially non-functional devices shipped outside the EU for legitimate reasons.

These rightful shipments of non-functional medical devices would be declared illegal and would probably be destined to be unnecessarily wasted.

The proposed amendment would encourage the already well-established practice of refurbishing and re-use that helps provide quality healthcare at affordable costs in Europe.

COCIR proposed amendment 2:

Annex IC. c)

"c) a declaration made by the holder who arranges the transport of the electrical and electronic equipment that none of the ~~material~~ or equipment within the consignment is waste as defined by Article 3(1) of Directive 2008/xx/EC on waste, and"

Rationale: This amendment would ensure consistency between Annex IC and the WEEE Directive that applies only to equipment