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# Reprocessing, products liability, and other issues

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- (31) ‘fully refurbishing’, for the purposes of the definition of manufacturer, means the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, **to bring it into conformity with this Regulation, combined with the assignment of a new lifetime** to the refurbished device
- (39) ‘reprocessing’ means a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device



- Article 17: Single use-devices and their reprocessing
  - Only possible in countries where permitted by national law and in accordance with this article
  - Forbidden, permitted, not forbidden, .....
- Any person who is reprocessing such devices becomes the manufacturer of this device
- Health institutions may reprocess for their own needs, different rules may apply
- Rules are only valid for products according to (EU) 2017/745 or 93/42/EEC
- Member states may maintain or introduce stricter rules
- Some member states do not permit reprocessing (France), in other member states it is not forbidden, yet (Germany)



- Reprocessor becomes the new manufacturer
  - With the duty to comply with all applicable requirements as a manufacturer
  - Including labelling
  - Including risk management
  - Including creating a technical documentation, conformity assessment procedure, declaration of conformity
  - Including UDI requirements, registration requirements
  - Including clinical evaluation, PMS system, reporting system, ...



All indications, symbols, information required for the original device, in addition:

Name and address of reprocessor  
(name and address of original manufacturer disappears from label)

Name and address of original manufacturer needs to be mentioned in the instructions for use

On label: an indication that this device is a reprocessed device, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles



## Health Institutions:

- Health Institutions may reprocess their own single-use devices
- Rules of the MDR apply as it is not linked to “placing on the market” (make it suitable)
- Special rule may be provided by national laws in the future, deviating from the regulation

## Further distribution:

- Member states may introduce additional requirements which restrict or prohibit, within its territory, the following:
  - the reprocessing of single-use devices and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing
  - the making available or further use of reprocessed single-use devices





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# Thank you


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