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Legal Framework for 3D BioPrinting in Europe

1st International Conference of Digital Medicine & Medical 3D Printing

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Agenda

- Legal classification of 3D Printing
- Current regulation of various types of 3D Printing
- Intellectual Property Right Issues
- Data Protection Aspects
- Upcoming Changes

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Legal view on 3D Printing

- Production Facility
  - Production facilities for medical devices and medicinal products are regulated
  - EU-Directives and Regulations, national laws, ISO 13485
- Final Product
  - Regulated as medical device, ATMP or other product
- Raw Material
  - Raw material for medical devices and medicinal products are regulated
  - Harvest, storage, transport and use of biological material is regulated

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Legal view on 3D Printing

- Production Process
  - Quality system required for manufacturing process of medical devices and medicinal products
  - National competent authorities and Notified Bodies may classify design and production tools as medical devices, e.g. design software
- Personal Data
  - Personal (health) data might be collected, stored and used during manufacturing chain
  - Customization might link product to an individual person

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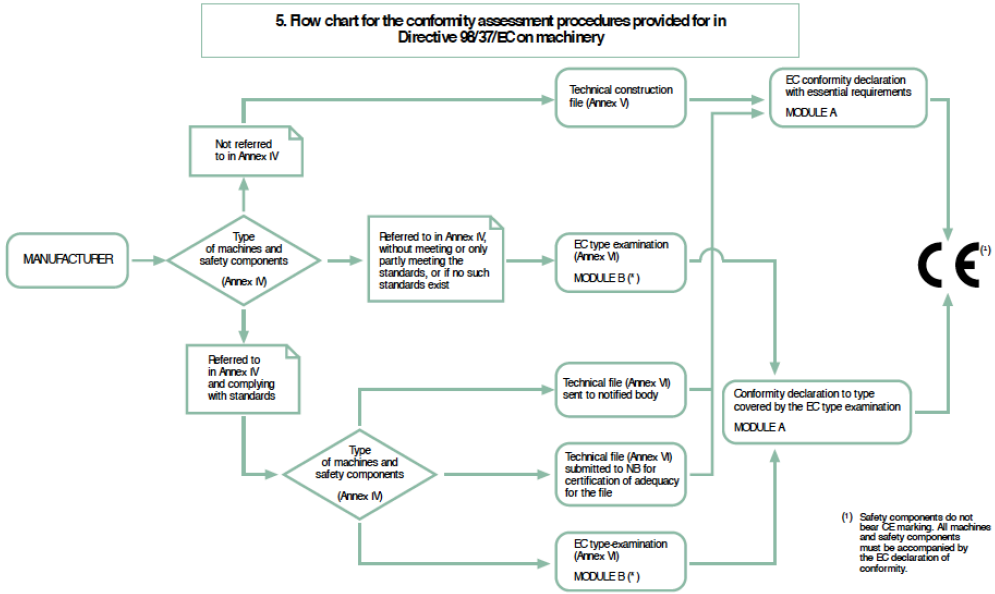
Production Facility

- Production Facility: 3D Printer
- Currently regulated under EU Machinery Directive 2006/42/EC



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Raw Material

- Chemical substances regulated under Regulation 1907/2006 (REACH)
- Living cells and tissues regulated under Directive 2004/23/EC
- Special rules apply to medical devices manufactured utilizing animal tissue (Commission Regulation 722/2012)

Final Product

- Can be a medical device or an accessory to a medical device and regulated under Directive 93/42/EEC

- Can be an ATMP and regulated under Regulation 1394/2007

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Final Product

- Can be a medicinal product and regulated under Directive 2001/83/EC

- Can be none of the aforementioned categories
  - Pre-op models
  - Tissue models for research, drug discovery

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Medical Device Law

- Current position of regulators: custom-made medical devices
- Prescription by physician defines the features of the final product
- Production technique is standardized

Medical Device Law

The Manufacturer has responsibility for the design, manufacture, packaging & labeling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person or on his behalf

Responsibility	Surgeon	Hospital department	Printer	Printer Manufacturer
Design	Possible	Possible	No	No
Manufacture	No	Probable (if the department issues specifications)	Possible, but probably a sub-contractor to the dental lab	Unlikely, unless the printer (and consumables) tailored to the one-off production of specific device(s)
Packaging & labelling	Unlikely	Possible	Possible	No
Placing implant on the market under own name	Possible	Probable	Unlikely, but consider possibility of "*Intel Inside*"	No

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ATMP Regulation

- Tissue Engineered Product or a Combined ATMP
- If a product contains viable cells, it is an ATMP even if the principal mode of action is structural
  - Reversal of standard rule for medical device vs medicine
- Unlikely to be a “mere graft” unless cells (or tissues) are
  - minimally manipulated; and
  - used for same essential function
- Could argue that autologous product is not *placed on the market*
- Could argue that not manufactured within an *industrial process*

GMP Requirements

- Current ATMP GMP requirements assume a central manufacturing facility
- Unpractical for bedside 3D printing
- National Competent Authorities are risk averse
- Consider “Hospital Use Exemption” rules (especially in Germany and Spain)
  - Does not require trial data
  - Requires GMP “equivalence”
  - Can charge patients for therapy
- ATMP Regulation scheduled for revision
  - Could change autologous and combined ATMPs

Intellectual Property

- Copyrights for
  - Software
  - Software model for device or body part

- Patents for
  - Printing method
  - Final product
  - Printing materials

- Human body itself cannot be a patentable invention
- Elements isolated from the human body or otherwise produced my technical processes may constitute a patentable invention

- Various competing solutions to attempt to resolve IP issues

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Personal Data

- 3D printing involves collection, processing and storing personal health data
- Data controller has regulatory requirements, such as data processing agreement with third parties
- Personal health data might be exported outside the EU
- Some of the existing Guidance Documents by Working Party are relevant for 3D printing

Upcoming Changes

- New EU medical device law regulation in 2016
- New EU data privacy regulation coming soon

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