



Legal Framework for 3D BioPrinting in Europe

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Medical 3D Printing

Dr. Mathias Klümper

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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



Legal view on 3D Printing

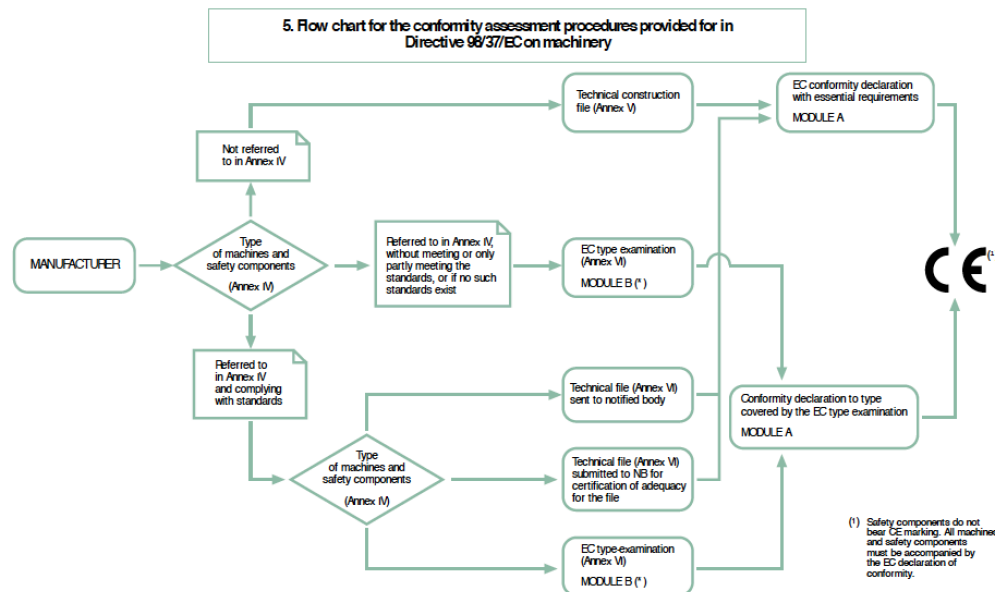
- Production Facility
 - Production facilities for medical devices and medicinal products are regulated
 - EU-Directives and Regulations, national laws, ISO 13485
- Final Product
 - Regulated as medical device, ATMP or other product
- Raw Material
 - Raw material for medical devices and medicinal products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

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

Production Facility

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

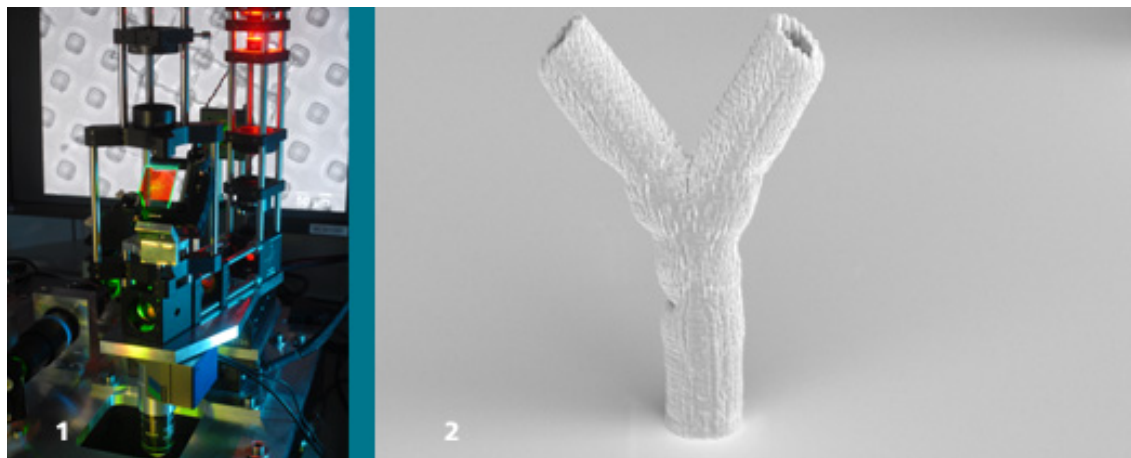


(1) Safety components do not bear CE marking. All machines and safety components must be accompanied by the EC declaration of conformity.

(*) These procedures were approved before the adoption of Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.

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

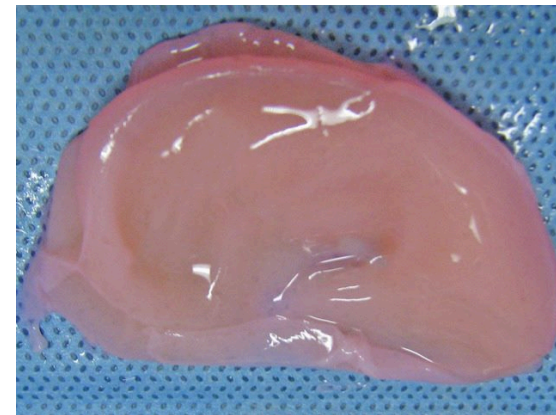
- Can be a medical device or an accessory to a medical device and regulated under Directive 93/42/EEC

3D Printed Handie Prosthetic Hand Costs Less Than \$400

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

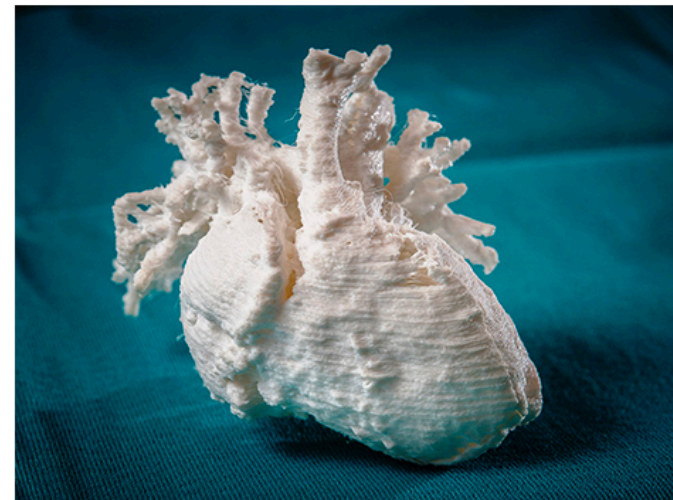


Final Product

- 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

Een baby van drie maanden met een complexe hartafwijking heeft eind vorig jaar in het LUMC een unieke operatie ondergaan. Voor het eerst in Nederland gebruikten de behandelaars namelijk een geprint 3D-model van het hart om de operatie voor te bereiden. Hierdoor gaat er in de operatiekamer geen kostbare tijd verloren.

Het meisje werd afgelopen zomer geboren met een complexe hartafwijking. Een operatie was nodig om een gat tussen de hartkamers dicht te maken. Onduidelijk was of haar hart zou kunnen functioneren met twee kamers, of dat er een eenkamerhart gemaakt moest worden. Met een tweekamerhart is de kwaliteit van leven beter en de levensverwachting hoger.



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



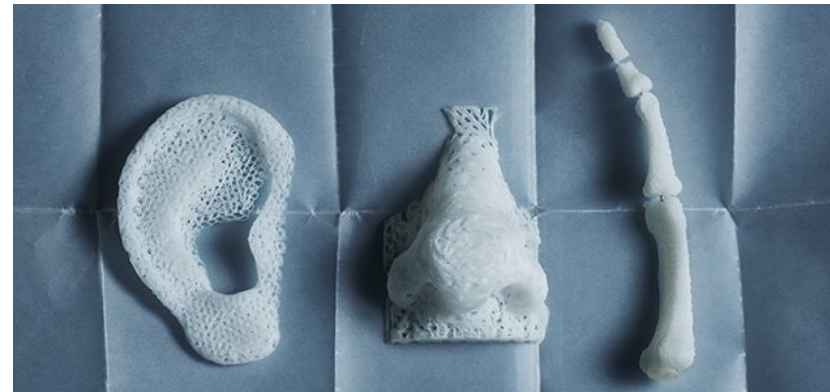
Medical Device Law

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

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 by technical processes may constitute a patentable invention
- Various competing solutions to attempt to resolve IP issues

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

Dr. Mathias Klümper

Lützeler Klümper
Partnerschaft von Rechtsanwälten

Domstraße 10
20095 Hamburg

Tel. +49 40 18024892 0
Fax: +49 40 18024892 9

kluemper@gerricus.com



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