Overview of the regulatory framework for 3D printed dental implants

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How the law sees 3D printing

There must be a production process that can be regulated

- Manufacturing processes for medical devices require a quality management system
- Components for devices are regulated (and need to be covered by the QMS)
- Medical devices production facilities are regulated (GMP, ISO 13485)
- National Competent Authorities and/or Notified Bodies may consider the design/production tools to be medical devices (e.g. design software or printers tailored for dental)

Holding and using data related to an identified or identifiable person

- Collection and processing of personal data concerning health
  - Customisation links objects to persons
- Data can be breached, stolen etc
Uncomplicated Scenario

1. Dentist prepare a prescription for an implant
2. Dental lab receives prescription from Dentist, along with an impression of the site where it is to be fitted
3. Dental lab establishes a data model of the base on which the implant is to be built and its environment and designs the implant using CAD software
4. Dental lab sends prescription to the Printer requesting a dental structure that conforms to the lab's design and specifications
5. Printer manufactures the dental structure on the basis of this data (using materials sourced by the Printer) and sends it back to the lab
6. Dental lab finishes the implant (may include dying, application of ceramic, polishing ...) and supplies the finished product to the dentist
7. Dentist fits the finished product to the patient
“Background” Regulations

• The Printer as a Machine
  – The Machinery Directive (2006/42) applies to the printer itself

• Materials used in the process
  – REACH (1907/2006) for the chemical substances used in the printed article
  – Intermediate material to be printed may constitute medical device under current Commission guidance for custom-made devices
    o See CE Marked intermediate materials such as LaserPFM Cobalt Chrome owned by Renishaw
Regulation of the printed implant

• Default regulatory position is that dental “implants” are custom-made medical devices
  – Prescription (or specification) defines end result but production technique is standardised
  – Question: what is “custom-made” about a 3D printed medical device using a standard 3D printer?

• MHRA assumes that the “prescriber” of a dental appliance is the dentist and that the dental lab is the “Manufacturer”

• In the absence of a clear allocation of responsibility, various entities involved in the process could be considered to be the legal manufacturer
  – Printer or the Dentist could be considered to be the “manufacturer”
Who is the manufacturer of a 3D printed dental implant?

The Manufacturer has responsibility for the design, manufacture, packaging & labelling 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.

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Dentist</th>
<th>Dental lab</th>
<th>Printer</th>
<th>Printer Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design</td>
<td>Possible</td>
<td>Possible</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Manufacture</td>
<td>No</td>
<td>Probable (as the lab issues specifications)</td>
<td>Possible, but probably a sub-contractor to the dental lab</td>
<td>Unlikely, unless the printer (and consumables) tailored to the production of specific dental implants</td>
</tr>
<tr>
<td>Packaging &amp; labelling</td>
<td>Unlikely</td>
<td>Possible</td>
<td>Possible</td>
<td>No</td>
</tr>
<tr>
<td>Placing implant on the market under own name</td>
<td>Possible</td>
<td>Probable</td>
<td>Unlikely, but consider possibility of “Intel Inside”</td>
<td>No</td>
</tr>
</tbody>
</table>
The Manufacturer of a custom-made medical device must …

• Custom-made medical devices do not need to comply with all of the aspects of the Medical Device Directive (e.g. a CE Mark, a Notified Body or a formal IFU)

• However, they must comply with the broad framework for medical devices

• The manufacturer must:
  – register with the MHRA (or national competent authority)
  – establish systems for post-marketing surveillance, vigilance and corrective action
  – hold records for implantable custom-made medical devices for 15 years
The Manufacturer of a custom-made medical device must …

• The manufacturer must review all the requirements of the Directive ... against their procedures, including:
  • data allowing identification of the device, i.e. description, serial or order number ...
  • a statement that the device is intended for exclusive use by a particular patient, together with the name of the patient (this may be an identification number if patient confidentiality needs to be maintained, provided it can be traced ... to the named patient)
  • the name of the medical practitioner who made out the prescription and their place of work
  • the features of the device as specified in the relevant prescription, i.e. the written prescription with its special features extracted to define the particular device
  • a statement that the device conforms to all the relevant Essential Requirements set out in Annex I and, where it does not, the grounds for believing it is safe for use
  • the name and address of the manufacturer
Regulation of the activity

- Quality management system requirements / GMP requirements
Regulation of the activity

Some notified bodies have started requesting CE marking as standalone software medical device of

- final product design software
- customer requirements fine-tuning collaboration software

IMHO unlawful approach – regulation of production tools as medical devices that will be placed on the market
Draft Regulation for Medical Devices

• No specific provisions regarding 3D printing
• Proposal to exclude mass produced customised devices from scope of custom-made devices
  • Implant would need to be CE Marked
• Increased standards for general (not custom-made) 3D printed medical devices by introducing stricter requirements re:
  • registration and use of notified bodies;
  • identification (UDI) and traceability; and
  • QMS and PMS
• Proposal to allow hospital in-house manufacturing of medical devices
• Hospital 3D printing likely to increase
Personal data

Activities related to 3D printing involve “processing” of “sensitive” personal data on many levels

- Data from hospital’s electronic health records
- Generation of patient related data for end product
- Data in files describing the final product...

Who controls the data?

- Controller has regulatory burden, must conclude processing agreement with others that have access to the data
  - Could be limited to the clinician if anonymised when provided to Lab
  - Could be Lab or anyone downstream if not anonymised

Where is the data?

- External printing lab?
- Hosted?
- Exported outside the EU for e.g. modeling / printing?
  - Safe Harbour?
  - Consent?
Personal data

Current EU guidance relevant for 3D printing:

• Personal data as concept
  • WP 136 on concept of personal data
  • WP 192 on facial recognition

• Personal data concerning health
  • WP 131 on the processing of personal data relating to health in electronic health records (EHR)
  • WP 189 on eHealth and privacy
  • Letter of WP29 of 5 February 2015 on health data

• Biometric data
  • WP 80 working document on biometrics
  • WP 193 on biometric data
New Data Protection Regulation will be challenging for 3D

Different definitions for biometric data and data concerning health:

- 'biometric data' means any **personal data** resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of an individual which allows or confirms the unique identification of that individual, such as facial images, or dactyloscopic data

- 'data concerning health' means **personal data** related to the physical or mental health of an individual, including the provision of health care services, which reveal information about his or her health status

Data collected in connection with 3D printing will fall within both of these definitions

Definition of *Biometric data* does not relate to the purpose for which the data was collected (ie data collected [or even processed] for the purpose of confirming the unique identification of an individual): will be *Biometric Data* if allows identification
New Data Protection Regulation will be challenging for 3D

Article 9 prohibits processing of both these categories of “sensitive personal data” (albeit with a purpose limitation in the case of biometric data)

The processing of personal data, revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of genetic data, biometric data in order to uniquely identify a person or data concerning health or sex life and sexual orientation shall be prohibited.

While there are various exemptions to this prohibition (such as medical treatment or research), the exemptions are likely to differ depending whether the data is “biometric” or “data concerning health”

The same data could have two different regulatory requirements
New Data Protection Regulation will be challenging for 3D

Consent will be challenging:

• The controller bears the onus of proving that consent was legitimate

• Consent to the processing of the data must be clearly distinguishable from any other matters, using clear and plain language

• Consent must be freely given, consent should not provide a valid ground for the processing of personal data, where there is a clear imbalance between the data subject and the controller

• Consent is presumed not to be freely given, if it does not allow separate consent to be given to different data processing operations despite it is appropriate in the individual case
Thank You

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