3D printing in medicine: regulatory and legal challenges

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The following provides an overview of recent regulatory and legal challenges in the EU with the new MDR (Medical Device Regulation).
Currently there is no official EU-Directive for 3D printing of medical devices. It can be noted that 3D printers and software intended for medical purposes are medical devices. Although there is no specific regulation for additive manufactured medical devices, under the MDD („Medical Device Directive“) patient-specific 3D printed devices are not qualified as mass produced but as „custom made“ devices (Art. 1 No. 2(d) MDD). In this context the term „custom made device“ means any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient. These custom-made devices do not require conformity assessment procedure involving notified bodies nor any quality management system. The regulations of the new MDR will apply to May 2020, but also here 3D printing devices do not get a definitely status. Thus, scenarios for additive manufacturing must be subsumed under the general regulation in the MDR. The classification as „custom made-device" is highly relevant, because if a product is not covered by the term much higher regulatory requirements are placed on the manufacturer. Due to Art. 2 (3) of the MDR a "custom-made device" is any device

- specifically made in accordance with a written prescription of any person authorized by national law by virtue of that person‘s professional qualifications
- which gives, under that person‘s responsibility, specific design characteristics
- and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs
- however, mass produced devices which need to be adapted to meet the specific requirements of any professional user and devices which are *mass produced by means of „industrial manufacturing processes“* in accordance with the written prescriptions of any authorised person shall not be considered to be custom made devices.

With regard to "in house" hospital produced devices, the phrase "non-industrial scale" appears, but what does it mean? In the context of medicinal products (!), the European Court of Justice (EuGH) has ruled in its judgement dated 26.10.2016 (C-276/15) – „Hecht Pharma“) that, in view of the objective pursued by the legislator to protect public health, such phrases should not be interpreted narrowly. According to the court an industrial process is characterised in general by a succession of operations to obtain a significant quantity of a standardised product. In the light of these principles it seems appropriate to use a „risk based“ approach to demarcate „custom made devices“ from devices „produced by means of industrial manufacturing processes“ in the meaning of Art. 2 (3) MDR. This is also because the regulatory burden for custom-made devices is still low(er) and this is only justified if there is a lower risk for the health of patients with regard to the manufacturing and use of these devices. As a consequence, e.g. the manufacturing and use of a higher amount of 3D printed hip implants in a hospital might not be qualified as use of „custom made devices“ any more, even if the implants are produced in accordance with a written prescription of a doctor and which are intended for the sole use of a particular patient exclusively to meet their individual conditions and needs. The most relevant information for hospitals and industry associated with these legislative changes are as follows:

- new MDR definition of „custom- made“ devices: aim for bringing more devices out of the scope of „custom-made“ and into the „regular“ medical device regime (Art. 5 (5) MDR)
- Hospitals are allowed to print their own medical devices with less regulatory restrictions