3D printing in the dental industry

Position Paper

of the Federation

of the European Dental Industry (FIDE)

on dealing with custom-made devices according to MDR

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1. Foreword FIDE

Dental industry companies have a very high degree of innovation, as they invest above average in research and development. Currently, they assume a leading role in the area of additive manufacturing, also known as industrial 3D printing. The number of dental medical products fabricated using different 3D technologies is constantly increasing. The new possibilities of 3D printing for fabricating dental products, e.g. dentures, teeth, restorations etc. may, without exaggeration, be regarded as a technical revolution. In the process the most varied patient restorations are designed on the computer and built up three dimensionally layer by layer using different 3D printing technologies. Resins or metals are the main materials used. The aforementioned innovative strength and continuous further development of materials and processes ultimately provide users with the possibility of using precisely fitting products and shortening the treatment period to the necessary minimum.

As an increasing number of companies in FIDE are becoming involved with these 3D printing technologies, it seems a logical step to set up a working group focusing on mutual interests and objectives and concentrating on representing its aims to public and private bodies. The primary objectives are:

- Involvement and cooperation with relevant associations and industries. This includes in the first instance dentists (Bundeszahnärztekammer [German Dental Association]) and dental technicians (Verband Deutscher Zahntechniker-Innungen [Association of German Dental Technicians' Guild]).
- Public relations work of FIDE should focus on the subject of 3D printing. The objective of public relations is primarily to illustrate the perspectives of 3D printing and answer questions in relation to safe use of the product and consequently the reliability of 3D products.

2. Executive Summary

Modern, industrial manufacturing methods are being increasingly used throughout the entire medical device industry for fabricating medical devices. These are not only suitable for serial production of large batch sizes of the same types of devices, but also for economic fabrication of customised, patient-specific devices (so-called “custom-made devices”) in batch size n=1.

3D printing, in particular, has also been increasingly used in medical technology and more especially in dentistry for many years from an ecological and economical aspect because, among other things, it helps to preserve resources. At the same time, use of reliable and safe materials, procedures and products are necessary for the fabrication of custom-made devices to ensure that the fabricated devices have defined chemical and physical properties and are thus also safe to use. The manufacturers of medical devices must basically take responsibility and liability for these requirements.

With adoption of the new European Medical Device Regulation (Medical Device Regulation, EU 2017/745 - MDR), 05 April 2017, for the first time reference was made in legislative text to industrial procedures for the fabrication of “custom-made devices” and mass-produced medical devices. Art. 2, No. 3 Sentence 1 MDR thus defines the term “custom-made device”. A medical device then becomes a custom-made device if it is fabricated based on a written prescription for a single patient and exclusively meets specific design features, which produce the intended treatment benefits solely with this patient.

Furthermore, legislators define that devices, mass produced in industrial processes according to written prescriptions, are not custom-made devices. However, 3D printing is also used as an industrial CAD/CAM process for patient-specific medical devices (custom-made devices) without this being classified as mass-produced devices.

A written reply from the European Commission to an enquiry by the FEPPD (European and International Federation of Dental Laboratory Owners) provides additional confirmation of the statement that 3D printing can also be used for patient-specific medical devices (custom-made devices).

Based on this statement and current discussion, the objectives of the present FIDE paper are:

- To present 3D printing and its use based on dental applications.
- To illustrate and prove that 3D printing is suitable for the fabrication of patient-specific medical devices in batch size n=1 (custom-made device).

- To illustrate that the safety of the definitive/final, patient-specific medical devices is guaranteed by way of proven processes, pre-products and units, taking into consideration state-of-the-art technology and that the requirements of medical technology are met.

3. Introduction

3.1 Development of 3D printing in dentistry

3D printing is an additive shaping process in which objects are produced, which were designed in advance using a CAD programme (computer-aided design).

However, not all 3D printing is the same: this umbrella term stands for several, sometimes technologically very different additive processes, and also for a large number of materials used. All processes have in common that objects are completely "assembled" physically by joining the individual layers of the objects to be fabricated using material-specific melting and solidification processes. In the majority of cases additional post-processing is necessary, e.g. cleaning and post-curing, to achieve the desired properties of the material. A general overview of processes and materials used is shown in Figure 1.

Principle	Description	Materials	Abbreviation
Binder jetting	Application of a liquid binding agent to a powder material	e.g. sand, metal, ceramic	BJ
Direct energy deposition	Fusing of a material using directed (heat)energy	Metals, plastics	DED
Fused deposition modelling	Targeted dispensing of a material by way of a nozzle	Plastics, composites	FDM
Multi-jet modelling	Targeted dispensing of a build-up material in drops	e.g. wax	MJM
Vat photopolymerisation	Targeted curing of a liquid photopolymer using an energy source	e.g. plastics (including filled), wax	SLA, DLP
Selective laser melting	Targeted application of thermal energy in the powder bed.	Metal, plastics	SLM
Sheet lamination	Joining of material layers to form a component	e.g. metal, paper, plastics	SL

Table 1: List of different additive process categories, according to DIN EN ISO / ASTM 52900:2017-06.

3D printing technologies such as stereolithography (SLA), digital light processing (DLP) and selective laser melting (SLM) are mainly used in dentistry. Typical materials used for dental applications are mainly resins or metals, e.g. to fabricate restorations or accessories such as dental models. Figure 1 shows an overview of dental objects, fabricated using 3D printing processes.

Figure 1: Dental application of 3D printing (from left to right): custom impression trays, bite-raising appliances in clear resin, dental models, surgical stents and frameworks for removable dentures (source: BEGO).

Pioneers in the dental sector were mainly industrial manufacturing centres which fabricated, e.g. frameworks or dental models using 3D printing based on CAD data received from clients. Digitisation of the dental industry, expansion of extraoral and intraoral scanners, development of new, biocompatible materials and decreasing investment costs of 3D printers and related software solutions subsequently resulted in a significant increase in the range of applications of 3D printing in dentistry and dental technology.

Additive technologies have thus not only become integrated in dental laboratories and dental practices but have also enjoyed a high degree of acceptance in the dental industry and in particular by users. The most important milestones of 3D printing in the dental industry are listed in Table 2 below.

Year	Milestones
1981	Patent publication[1] by Dr. Hideo Kodama for a prototype system using liquid photoreactive resins
1986	Patent for stereolithography (US Patent 4,575,330) by Charles Hull
1999	Patent application for the fabrication of restorations and dental accessories using selective laser melting (SLM) process (BEGO, Germany)
2002	Market launch of SLM for dental laboratory frameworks (BEGO, Germany)
2003	Market launch of biocompatible SLA resins (FotoTec® SL.A) for medical technical application using 3D printing (Dreve, Germany).
2003	SLM production of restorations fabricated using Wirobond C+ (BEGO, Germany)
2006	Market launch of SLM-fabricated CoCr crown and bridge frameworks (Sirona, "infiniDent" central manufacturing, Germany)
2007	Market launch of SLM-fabricated crown and bridge frameworks (DeguDent, Germany)
2009	Market launch of SLA-fabricated dental laboratory working models based on intraoral measurement data (Sirona, Bensheim und Charlotte (NC), USA)
2011	Launch of SLM technique as additive fabrication process (Kulzer, Germany)
2014	Launch of Freeprint® materials for DLP printing of dental medical devices (DETAX, Germany)
2015	Launch of the 3D printing system VARSEO (BEGO, Germany)
2017	Launch of hyperDENT hybrid module allowing the combination of 3D printing and milling (Follow-me, Germany).
2017	Launch of the 3D printing system "cara Print 4.0" (Kulzer, Germany)

Table 2: Milestones 3D printing

[1] Kodama, H. (1981). Automatic method for fabricating a three-dimensional plastic model with photohardening polymer. Review of scientific instruments, 52(11), 1770-1773.

The dental industry today already provides a large number of biocompatible materials, units and processes for fabricating, e.g. patient-specific surgical stents, custom impression trays or even bite splints. Defined processes such as cleaning, post-curing or mechanical reworking are required to ensure that 3D printed objects obtain their chemical, physical and haptic properties. This is because all medical devices, which have direct contact with the human body, must fulfil defined functions, independent of whether mass produced or custom made. These are, e.g. fit and mechanical properties such as abrasion-resistance and biocompatibility.[2] [3] [4] [5] This makes it all the more important to give due importance to the entire fabrication chain, so that defined properties of the final product are fulfilled and undesired side effects are excluded as far as possible in accordance with state-of-the-art technology.

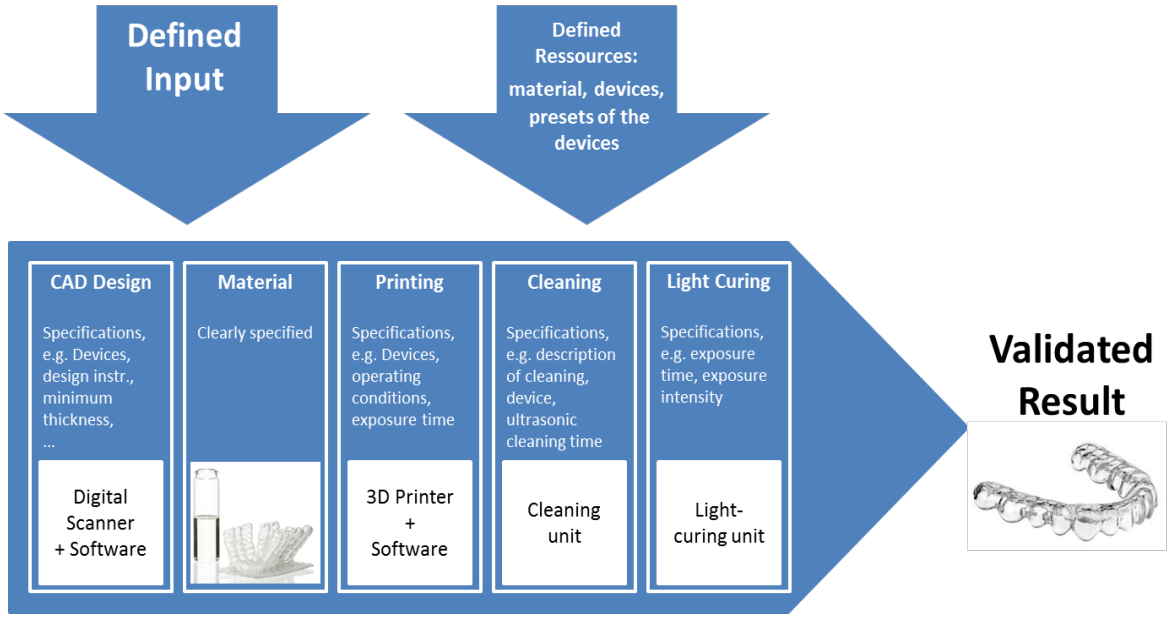


Figure 2: Fabrication chain of 3D-printed custom-made devices

[2] Neumeister, A. et al., Int. J. Comput. Dent. 2017; 20 (1): 35-51

[3] Neumeister, A. et al., Digital Dentistry 2017 (1): 22-28

[4] Wiese, H., Quintessenz Zahntech 2016; 42 (8): 1108-1117

[5] Glodecki, C. et al., Jahrbuch Digitale Dentale Technologien 2017: 87-95

3.2 Process flow for the fabrication of restorations: Comparison of conventional fabrication with fabrication using 3D printing based on the example of a crown

The basis for fabricating a crown is preparation of a tooth requiring a crown by the dentist. An impression is then taken of the prepared tooth and jaw of the patient, and also the bite and occlusion determined. This can be performed conventionally using an impression or digitally using an intraoral scan. The individual information record is transferred to the dental laboratory with additional patient-specific information such as tooth shade, material incompatibilities etc. Alternatively, the individual information record can be further processed directly by dentists if they use a so-called chairside CAD/CAM system or operate a practice laboratory in their own premises. The final shape of the crown is designed independent of the impression and fabrication process selected.

In conventional, analogue fabrication the crown is modelled out of burnout material, generally from wax. After producing a lost-wax pattern by investing and burning out the framework, the crown is pressed or cast. In digital fabrication processes the crown is designed on the basis of an intraoral or extraoral scan using stored datasets. The crown is then fabricated using modern fabrication processes such as using 3D printing. Further processing of the crown, e.g. polishing, is mostly required independent of the type of fabrication selected. The finished crown is then checked to ensure it corresponds to the required specifications. The entire sequence is represented graphically in Appendix I.

Both procedures produce custom-made devices in accordance with Article 2 Paragraph 3 MDR from the medical products used. This is due to the fact that the crown referred to in this example is fabricated in accordance with a *written prescription* for a *particular patient* and *exclusively meets the patient-specific design characteristics* and therefore produces the desired therapeutic benefits with the exclusive, particular patient. It also applies regardless of whether the custom-made device was fabricated conventionally or using an industrial manufacturing process. The regulatory discussion in relation to the European Medical Device Regulation (MDR) is explained in more detail in the following section.

4. “Custom-made device” in the dental industry according to MDR

4.1 Comparison of the Directive 93/42/EEC Medical Device Directive (MDD) and the European Medical Device Regulation (MDR)

The following comparison shows the changes to the European Medical Device Regulation (MDR) relating to the term “custom-made device” in the dental industry, which came into force 25 May 2017. Previous and new definitions are compared below.

Previous Directive 93/42/EEC (MDD), Art. 1 Para. 2, lit. d):	**New Medical Device Regulation (MDR) Art. 2, No. 3,:**
“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. The abovementioned prescription may also be made out by any other person authorized by virtue of his professional qualifications to do so. Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user shall not be considered to be custom-made devices;	“custom-made device” means any device specifically made in accordance with a written prescription of any person authorised 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

Table 3: Comparison of previous and current definitions of custom-made devices

From the point of view of the German dental industry, German dental practices and German dental laboratories the amendments of the MDR regarding industrial processes,

shown in Table 1 above, do not have any effect on the fabrication of custom-made devices using 3D printing. The reason for this is as follows:

- Art. 2, No. 3, Sentence 1 of the MDR defines the term “custom-made device”. A medical device is always a custom-made device if it is solely fabricated for a particular patient, meets specific design characteristics and produces the desired therapeutic benefits. In this respect there is no difference in content to the previously valid MDD.
- The second sentence (Art. 2, No. 3, Sentence 2 of the MDR) differentiates custom-made devices from medical devices which are mass-produced by means of industrial manufacturing processes. According to the MDR these devices are not custom-made devices. In the dental industry, however, there is no mass-produced device with the patient-specific prescription despite the use of industrial processes, e.g. 3D printing, as a custom-made device is always fabricated in the batch size n=1.

Conclusion: As patient-specific devices are not mass produced with dental 3D printing, even if this occurs in industrial manufacturing processes, these 3D-printed medical devices remain custom-made devices according to the MDR.

4.2 Statement of the European Commission regarding the European Medical Device Regulation (MDR) and fabrication of restorations using CAD/CAM

In a recently published statement by the European Commission (Ref. Ares (2017) 4450987-12/09/2017) to an enquiry by the European and International Federation of Dental Laboratory Owners FEPPD the Commission clarified what effects the new Medical Device Regulation (MDR) will have on custom-made devices and the use of CAD/CAM processes. The commission stated:

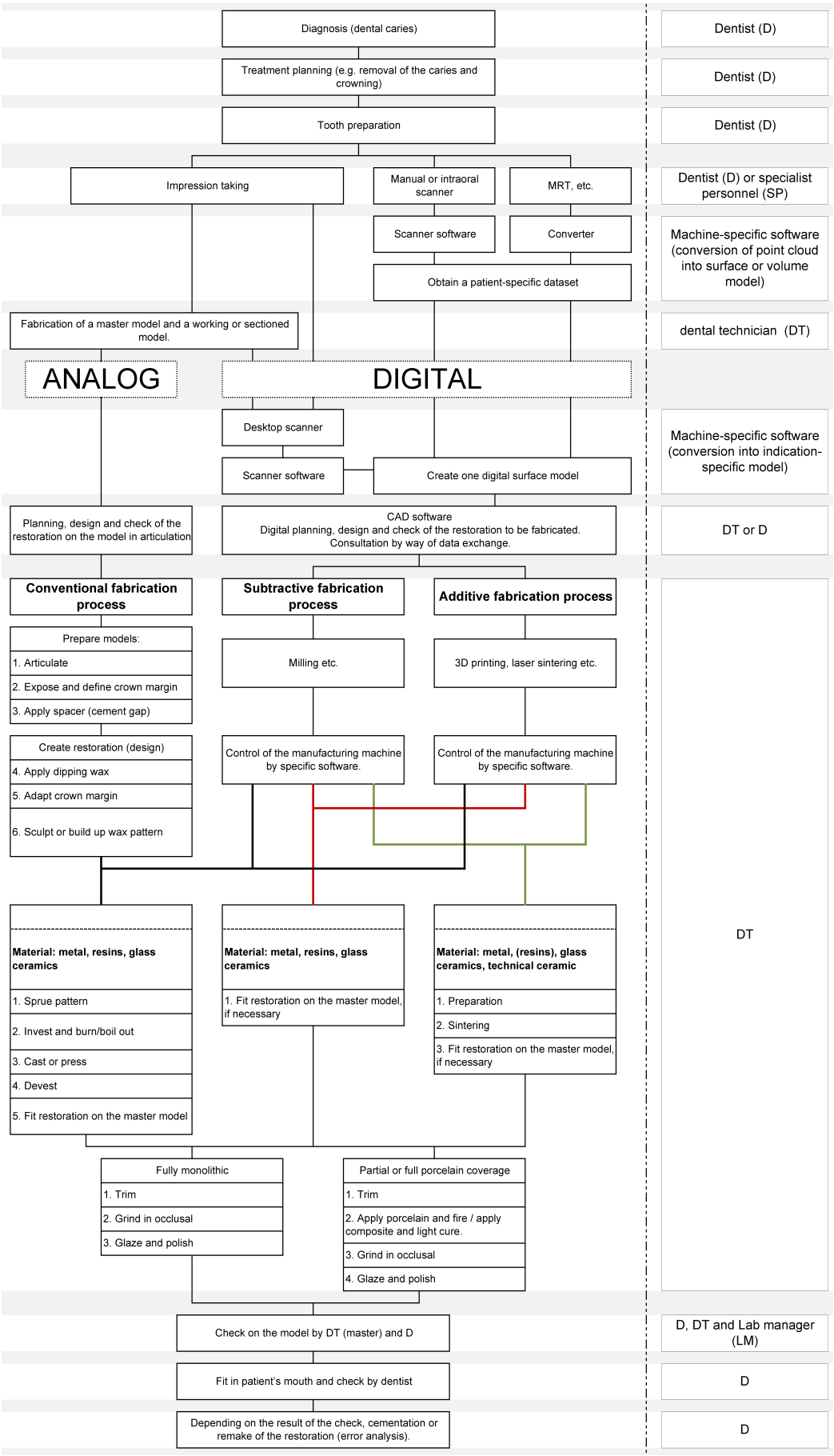
- Dentists and dental technicians who fabricate a restoration using CAD/CAM are manufacturers according to the definition in Art. 2(30) of the MDR.
- If a restoration is fabricated using CAD/CAM processes, this manufacturing method falls within the scope of the MDR.
- If a medical device is fabricated for a specific patient based on a written prescription, it is always a custom-made device in accordance with Art. 2(3). In this case, it is

sufficient that the exclusive, specific design characteristics produce the desired therapeutic benefits solely with that patient. The manufacturing method is irrelevant.

Concluding remark

The comments by the European Commission from 12 September 2017 reinforce the position of the FIDE 3D printing working group, that fabrication of patient-specific medical devices (custom-made devices) using industrial CAD/CAM processes such as 3D printing can be produced in German dentistry and dental technology in the proven quality, without them being differently classified as mass-produced devices. The production of custom-made devices takes place within the framework of proven 3D-printing processes and underlines the safe fabrication of patient-specific medical devices using 3D printing.

5. Appendix I


Diagnosis (dental caries)
Dentist (D)
Treatment planning (e.g. removal of the caries and crowning)
Dentist (D)
Tooth preparation
Dentist (D)
Impression taking
Manual or intraoral scanner
MRT, etc.
Dentist (D) or specialist personnel (SP)
Scanner software
Converter
Obtain a patient-specific dataset
Machine-specific software (conversion of point cloud into surface or volume model)
Fabrication of a master model and a working or sectioned model.
dental technician (DT)
ANALOG
DIGITAL
Desktop scanner
Scanner software
Create one digital surface model
Machine-specific software (conversion into indication-specific model)
Planning, design and check of the restoration on the model in articulation
CAD software
Digital planning, design and check of the restoration to be fabricated.
Consultation by way of data exchange.
DT or D
Conventional fabrication process
Subtractive fabrication process
Additive fabrication process
Prepare models:
1. Articulate
2. Expose and define crown margin
3. Apply spacer (cement gap)
Milling etc.
3D printing, laser sintering etc.
Create restoration (design)
4. Apply dipping wax
5. Adapt crown margin
6. Sculpt or build up wax pattern
Control of the manufacturing machine by specific software.
Control of the manufacturing machine by specific software.
DT
Material: metal, resins, glass ceramics
1. Sprue pattern
2. Invest and burn/boil out
3. Cast or press
4. Devest
5. Fit restoration on the master model
Material: metal, resins, glass ceramics
1. Fit restoration on the master model, if necessary
Material: metal, (resins), glass ceramics, technical ceramic
1. Preparation
2. Sintering
3. Fit restoration on the master model, if necessary
Fully monolithic
1. Trim
2. Grind in occlusal
3. Glaze and polish
Partial or full porcelain coverage
1. Trim
2. Apply porcelain and fire / apply composite and light cure.
3. Grind in occlusal
4. Glaze and polish
Check on the model by DT (master) and D
D, DT and Lab manager (LM)
Fit in patient's mouth and check by dentist
D
Depending on the result of the check, cementation or remake of the restoration (error analysis).
D

6. Authors

FIDE

- Dr. Markus Heibach, Executive Director, FIDE
- Gregor Stock, Head of Technical and Legal Affairs Department, FIDE

Members of the FIDE 3D printing working group

- Dr. Ceno Agena, Detax, Ettlingen, Germany
- Dr. Reiner Altmann, Dreve, Unna, Germany
- Dr. Jens Becker, Kulzer, Hanau, Germany
- Michael Breer, Dreve, Unna, Germany
- Dr. Juliane Gösling, BZÄK (German Dental Association), Berlin, Germany
- Martin Hesselmann, Shofu, Ratingen, Germany
- Dr. Hans-Dieter Höhnk, DMG, Hamburg, Germany
- Hansgeorg Kaul, Amann Girrbach, Koblach, Austria
- Dr. Armin Kirsten, VITA, Bad Säckingen, Germany
- Michael Krause, Scheu Dental, Iserlohn, Germany
- Dr. Jens Nagaba, BZÄK, Berlin, Germany
- Markus Nordmann, VOCO, Cuxhaven, Germany
- Michael Prehn, VDZI, Berlin, Germany
- Daniel Reitel, Reitel Feinwerktechnik, Bad Essen, Germany
- Frank Rosenbaum, GC Europe, Bad Homburg vor der Höhe, Germany
- Dr. Christian Schmidt, Dentsply Sirona, Bensheim, Germany
- Dr. Klaus-Peter Stefan, 3M Deutschland, Seefeld, Austria
- Dennis Wachtel (Chairman of the 3D printing working group), BEGO, Germany
- Arne Westmeier, Scheu Dental, Iserlohn, Germany

7. References

[1] Kodama, H. Review of scientific instruments, 1981; 52: 1770-1773.

[2] Neumeister, A. et al., Int. J. Comput. Dent. 2017; 20 (1): 35-51

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