

Overview **about the scope of duties and main activities of FIDE**

Years under review: 2005-2019

I. Introduction

FIDE represents around 550 large, medium-size and small companies in 10 European countries. These companies cover the complete range of industrial products for use by dentists and dental technicians. In light of the increasing international complexity and the global competition, FIDE undertakes its role as a “global player” on behalf of its members in the area of European interests. FIDE remains focused on cooperation and teamwork with relevant European and international associations. Moreover, opportunities for the advancement of the European dental market are deliberated and researched.

II. Aims and missions of FIDE

FIDE is the voice of the European dental manufacturing industry. The aims of FIDE are to represent the common interests of the European dental manufacturers associations and to promote their co-operation. FIDE represents the dental manufacturers in the area of medical legislation and standardisation and promotes and improves the availability of dental market data.

Main aims of FIDE are:

- Liaison with the Institutions of the European Communities
- Representation of the dental industry at international bodies
- Representation of the dental industry at governments
- Relationship with the European associations of dealers, dentists and dental technicians
- Technical harmonisation and standards
- Common trade policy
- International exhibitions and congresses
- Annual European dental market survey

III. Communication and collaboration with partner organisations

FIDE maintains relations to all international associations of the dental field. In detail, these organisations are:

a.) ADDE

ADDE is the Association of Dental Dealers in Europe. The European Dental Business Committee (EDBC) is a joint body composed of the executive boards of FIDE and ADDE. This body meets annually. The meetings serve as an exchange of experiences and opinions on topics which are relevant to both manufacturers and trade. Discussions and debates focus on potential joint measures in reaching common goals. Recurring themes were the

revision of the European medical device legislation, requirements of the unique device identifier (UDI), Minamata Convention on mercury, working group "Radiology", water quality, waste disposal, questions of technical law and regulation and the international exhibition schedule.

b.) IDM

FIDE is a member of the International Dental Manufacturers (IDM). IDM represents as an association the global interests of the manufacturing industry before governments and professional dental organisations and coordinates the joint international interests and benefits of the regional member industry associations. The IDM General Assembly meets two times a year, generally on occasion of the annual FDI-congress or the International Dental Show (IDS).

c.) FDI

FIDE and IDM cultivate a good relationship to the international dentist organisation FDI (World Dental Federation). Main topics in the regular meetings are the exchange of information and the exchange of views about the venue of the annual FDI congress.

Because some of the FDI congresses in the past were not very successful for the industry, IDM members installed the Congress Committee Task Team (CCTT). This group discussed in several telephone conferences on the future of FDI Congresses. IDM and FIDE are in the opinion that FDI needs a professional experienced business partner with business ideas for the organization of congresses. The success of FDI congresses primarily depends on the attendance of regional dentists.

The venues of the next FDI Congresses are: 2018 in Buenos Aires and 2019 in San Francisco.

d.) FEPPD

FEPPD is the European and International Federation of Dental Technician Laboratory Owners. FIDE supports current projects of FEPPD, such as "Leonardo da Vinci" or "DOSAM".

e.) ISO TC 106

The "ISO / TC 106 - Dentistry is the Technical Committee on Dentistry, of the International Organization for Standardization. FIDE works in liaison with ISO TC 106. The meetings of ISO TC 106 and its subcommittees take place once a year. Main goal of the Committee is to develop standardization of terminology, test methods and specifications for materials, instruments, dental equipment and other devices used in all segments of Dentistry. To date, more than 160 standards were developed by the TC-106 and the subcommittees and have been published by ISO. About 350 experts and delegates (generally up to 10 representatives from FIDE) regularly attend the meetings of ISO/TC-106.

f.) CEN TC 55 Dentistry

The European Standard Committee CEN is responsible for all standardisation tasks in the dental area in Europe. The Committee consist of six subgroups (working groups) which deal with the topics classification, biological evaluation and testing, nomenclature for medical devices used in dentistry, dental alloys, risk assessment related to dental materials. Additional working group is the Steering Committee. FIDE representatives are active in all working groups and are responsible for the development of standards setting safety, quality and performance requirements for medical devices that are put on the European market. Decisions are prepared in regularly meetings.

IV. Regulatory Affairs

The importance of regular and sustained coordination at the European and international level is demonstrated by the various themes and of challenging topics that were under discussion in the business meetings. The impact of the decisions taken by these bodies – whether fundamentally political or material and operational - may not always be immediately noticeable to firms, which are members of the national associations within FIDE. As opposed to individual firms, the associations that make up this federation are authorized as participants or dialog partners.

In many areas, owing to the participation, input and influence of the associations in Brussels, as a counterpart to their associates in Europe or abroad, to organisations such as IDM, FDI or institutions outside of the dental branch, – agreements are concluded. The end results facilitate individual firms' activities in the market, or actually open new markets.

Main topics in the last years were:

a.) Revision of the European Medical Device Legislation

On 26th September 2012 the European Commission presented the draft revision of the European Medical Device Act. It provides for numerous changes in existing regulations, which are also welcomed by the industry, to further increase patient safety. However, the draft also contains new rules that do not provide additional benefits for the safety of the products and patient protection but have massive negative effects on the entire medical technology industry, which consists predominantly of small and medium enterprises.

In the time 2012 to 2016 FIDE and the dental industry (on national and European level) developed several position papers and statements and conducted many personal discussions with Members of the European Parliament and national authorities. In all cases the goal of FIDE was to present solutions with less impacts for the dental industry.

The final version of the new Regulation on Medical Devices (MDR) was published on 5 May 2017 in the Official Journal of the European Union. After a transition period of three years it shall apply from 26 May 2020. Several requirements of FIDE were fulfilled in the text. First of all the legislator changed the rule 19 and presented a version which classifies medical devices containing nanomaterials according their internal exposure in class IIa (negligible exposure), IIb (low exposure) or III (middle or high exposure). Additionally there will be no approval procedure (comparable with FDA approval) in Europe and there will be exemptions for dental implantable devices concerning the implant card. But manufacturers may not ignore that they will be faced with a lot of new requirements, e.g. Implementation of UDI, higher documentation required (technical documentation, clinical evaluation), rigorous post-market surveillance, scrutiny process for high-risk devices and other.

In 2018 the problem that there are not enough Notified Bodies available, became apparent. Manufacturers see an explicit bottleneck. Fact is that in 2014 there were round about 90 notified bodies, today only around 50. For the accreditation according the new MDR, 37 Notified Bodies so far have applied. This number is definitely too little, because these notified bodies will have to certify significantly more products in future than before. In addition, there will be higher classifications and the individual tests are also extensive.

To avoid negative effects, national and European medical device associations (FIDE too) sent several letters to the ministries of health and informed that it is urgently necessary for this development to be taken up at EU level and for the EU Commission to be called upon to come up with timely solutions. It is not only the date of validity of the new regulations that is approaching, but also the end of the electoral period or term of office of the European Parliament and the Commission in 2019.

In October 2018 stakeholders were invited to apply for participation as observers in the new subgroups of MDCG. Several representatives of dental manufacturers sent their application to the Commission. Today FIDE is member in all important subgroups.

b.) Nanomaterial

The EU-Commission deals intensive with this topic since summer 2010 and started a first hearing with several questions about the use of nanomaterial in products. From this time all questions relating to "nanomaterial" became the most important issue for FIDE and FIDE member associations.

In a first step, FIDE established a working group "Nano" and released several very comprehensive statements on the classification rule 19 (medical devices containing nanomaterial). This group is the basic dental committee for all further statements and activities.

aa.) In 2013/2014 there were three public consultations relating to the complex "nanomaterial", initiated by the EU-Commission and the Scientific Committee of the Commission. FIDE participated in all three consultations and gave detailed statements to the draft opinion of the Committee. The surveys tended to the question whether the release of nanoparticles during the use could have potential risks for the patients. After evaluation of all statements the Committee will present a final report.

bb.) FIDE aims to get access and to become member in all-essential Committees of the Commission that deal with the topic "nanomaterial". In the last two years FIDE succeeded in becoming member in three important Committees:

- Working group "New and Emerging Technologies": Nanotechnology is one of the new technologies
- Working group "review of the definition of the term nanomaterial"
- ISO TC 194 (clinical trials), working group "nanomaterial": This group has the mandate to develop a standard for biological tests in special consideration of the release of nanoparticles from dental medical devices

cc.) In 2014, FIDE developed a detailed overview about the identification of those products that could be affected by the definition of the term nanomaterial and by classification rule 19. In a substantial comparison FIDE pointed out that according to the actual legislation nearly 6 % of dental medical devices are in class III. Should the proposal of the Commission be set into force, more than 60 % of all dental medical devices will be classified as class III products.

dd.) In 2016/2017 (in connection with the finalisation of the new Medical Device Regulation) FIDE started the assessment of the question how to classify dental medical devices containing nanomaterials under the new classification rule 19. From the view of FIDE most of these products should be classified as class IIa devices because their internal exposure can be evaluated as "negligible".

In September 2018 the dental working group "nanotechnology" adopted a paper on "Frequently Asked Questions" on Rule 19. This document is intended to be used at European level as a basis for the development of a Guideline on Rule 19. The Commission mandated the working group NET (FIDE is member of this group) to generate the first draft.

c.) Medical Devices containing silver

The EU-Commissions' working group "borderline and classification" has published in July 2014 a revised version of the manual on borderline and classification. Because silver is

acting as an antimicrobial agent the working group comes to the conclusion that medical devices containing silver should be classified as class III products.

Although the views expressed in this manual are not legally binding, dental manufacturers decided to object this opinion. In a detailed statement they stated that a higher classification is not justified. The amount of silver ions that could be released is very small and in all measures the principle of proportionality should be sufficient recognised. Concerned medical devices affected from this evaluation are dental filling materials (amalgams, silver-reinforced glass ionomers), silver-containing dental solders for orthodontics or precious metal dental alloys. They are used, among other things, in crowns, bridges, inlays, removable prostheses, brackets and treatment appliances for orthodontics, which come under the headings „dental prosthesis“ and „correction of tooth malpositioning“.

d.) Bisphenol A

The American Dental Organisation (ADA) published an article about Bisphenol-A (BPA) which received widespread media coverage.

Because dental materials (e.g. sealants, composites) may contain BPA, ADA informed about the safety and risks of BPA. ADA stated that the current evidence does not indicate a health risk related to the use of resin-based sealants and composites.

The Ministry of Health in Canada came to the result that BPA in baby bottles could be a risk and banned BPA in baby bottles. But the ministry also states that BPA in other products is without risks.

The European Commission and the Scientific Committee on Emerging Newly Identified Health Risks (SCENIHR) have launched at the beginning of 2014 a public consultation on the preliminary opinion “the safety of the use of bisphenol A in medical devices”.

The aim of this opinion is to assess whether the use of bisphenol A in medical devices could give reasons for concern from the health point of view and, if possible, to provide indications on limit values for BPA release from medical devices.

Dental manufacturers and FIDE evaluated this preliminary opinion and stated that the content of the Committees’ opinion is acceptable for the dental industry and that there will be no negative impacts.

SCENIHR will assess all comments from interested parties and published a final opinion in February 2015.

e.) Dental Amalgam

The strategy of the EU-Commission and the United Nations Environment Programme (UNEP) was to reduce the emissions of mercury in the environment. Also the question of a ban of amalgam was discussed. FIDE was asked by the Commission to collect information about the state of the art of restorative materials and evaluate the cost-benefit implications for patients of substituting dental amalgam with other alternative materials, such as composite resins, glass ionomers, other metals (alloys) and ceramics.

The result of the FIDE survey was: Dental amalgam is very durable, it is easier to use and it is cheaper than alternatives.

At the beginning of 2013 the EU-Commission and UNEP published their final decisions.

Based on the scientific opinions the EU-Commission informed that amalgam does not cause health risks for patients and users. Merely pregnant women and children as well as patients who are allergic should not be treated with amalgam. Therefore there are no reasons for a reduction of the use of amalgam. But amalgam should be used in future only in encapsulated form.

But the Commission is also in favour to promote the future use of alternative filling materials. In the moment the Commission has too little scientific expertise concerning the risks of alternatives. This is why the Commission asks all member states, stakeholders and manufacturers for support:

- to send any available data on safety of amalgam and on alternatives and
- to provide contribution on the necessity and level of use to assist the implementation of the International Instrument.

In a UNEP meeting in January 2013, Governments agreed to the text of a global legally binding instrument on mercury. This treaty was finalized and included important provisions to reduce and eliminate mercury pollution, one of them being a requirement for countries to phase down the use of dental amalgam (mercury fillings). The treaty, which has been under negotiation for four years, will require countries to undertake at least two of the prescribed steps to “phase down amalgam use.” Among those measures listed are these:

- Setting national objectives aimed at minimizing (amalgam) use
- Promoting the use of cost-effective and clinically-effective mercury-free alternatives;
- Encouraging professional societies and dental schools to educate and train dental professionals in the use of mercury-free dental restoration; and
- Encouraging insurance policies and programs that favour the use of quality alternatives to amalgam.

FIDE welcomes the outcome of the treaty. In the past FIDE campaigned for a reduction of the use of dental amalgam -versus a ban- through a greater focus on dental prevention and health promotion, increased research and development on alternatives and best management techniques for amalgam waste.

To ratify the Minamata Convention the EU Commission published its draft proposal of the mercury regulation in February 2016. Concerning dental amalgam the Commission decided that amalgam should be used only in capsuled form and that the use of amalgam separators in all dental surgeries should be mandatory.

In October 2016 the EU-Parliament voted on a complete ban of amalgam as per December 2022 (phase-out).

In December 2016 EU-Parliament, EU-Commission and EU-Council negotiated a compromise: The Parliament proposal for a full phase-out of amalgam did not survive these negotiations. All member states should set a national plan by 1 July 2019 on how they will reduce amalgam use. The EU-Commission will report by mid-2020 on the feasibility of phasing-out dental amalgam preferably by 2030 to be accompanied by a legislative proposal. But dental amalgam fillings are banned for children under 15 and for pregnant and breastfeeding women as of 1 July 2018.

FIDE members agree with this compromise.

All member states are obliged to develop a national implementation plan of the reduction of mercury up to mid of 2019.

f.) Tooth whitener and bleachings

EU-Commissions working group developed a paper relating to the classification of tooth whitener and bleaching as cosmetics or medical devices. In a “Manual on Borderline and classification in the community regulatory framework for medical devices” the working group proposed that these products should be considered as cosmetics. The reasons of the working group are that in some cases, in addition to other contributory factors, discoloration of teeth may be caused by a disease. But nevertheless discoloration of teeth is not considered to be a disease in itself. Besides, application of tooth-whitening products is not intended to treat the underlying disease; it only may mask a sign of an underlying disease.

FIDE members do not agree with this opinion. The amendment of the Cosmetic Directive 2011/84/EC did not change or amend the definition or the distinction line between the product categories cosmetic product and medical device. It just extended the possible range of cosmetic products for whitening teeth for aesthetic purpose up to products with concentrations of max. 6 % hydrogen peroxide present or released. As the new directive did not change the underlying classification, the above referenced court decisions are still in place and acknowledge the situation that in cases where tooth bleaching is required as a medical treatment these products are medical devices.

Therefore FIDE requests in a detailed statement in March 2013 a clarification that medical devices which fulfil the definition of Art 1 (2.) a.) of Directive 93/42/EEC are not affected by the amended Cosmetic Directive 2011/84/EC. The general limit of hydrogen peroxide present or released in cosmetic products for oral use based on a special risk evaluation for cosmetic products as products given to consumers and used by consumers directly is not applicable to medical devices in general. Medical devices follow different risk evaluations.

g.) REACH

The new chemical legislation "REACH" came into force on 1 June 2007.

Medical devices are not excluded from the substantial requirements of REACH. This means that the dental industry is completely affected by the new regulation. The main requirement of REACH is that if any producer, importer (from outside of the EU) or downstream user of chemical substances brings such chemical substances in quantities of one ton or more per year into the market, they are under obligation register with the new chemical agency in Helsinki.

For implementation of the new REACH regulation, all Member States are required to establish national "helpdesks", because specifically small and medium-sized companies need help in preparation for REACH.

In April 2007, FIDE informed all member associations as well as ADDE about the main content of the new regulation, highlighting the requirements and obligations under REACH.

New requirements relating to CLP (classification, labeling and packaging of substances and mixtures) will be set into force from 1 June 2015.

h.) Reprocessing

In August 2010 the European Commission published the report on the issue of reprocessing of medical devices in the European Union. The report is an assessment of the issue regarding public health, ethical, legal, economic and environmental aspects. The report does not contain any policy measures and the Commission confirms that such measures will be addressed within the context of the Recast of the Medical Devices Directives.

In the report, the EC recognises that the "reuse of single use medical devices may not be without risk from a public health point of view" and highlights the fact that "to date, no comprehensive study clearly demonstrates that reprocessing single use medical devices is globally a cost effectiveness and environmental friendly practice when done under high quality standards". The Commission also points out that in order to identify the potential risks associated with this practice the entire reprocessing cycle needs to be "evaluated and validated".

i.) Dental Fillers

COEN (compliance and enforcement group) is a working group within the European Commission (DG Sanco) and consists of members of the Commission and national competent authorities.

COEN invited dental manufacturers to an open meeting in February 2014. COEN stated that relating to the outcome of joint market surveillance activities on dental fillers there are three loopholes such as:

- a lack of complaints reporting: no complaint reported on dental fillers, which may indicate an underreporting by users,
- a lack of clinical investigation data: few data collected over a long period of time, a high number of references to published studies, and
- a lack of data on the nanoparticles used in dental fillers.

Subsequent to the meeting and in collaboration with several dental manufacturers FIDE sent an answer to COEN. FIDE stated that users and not manufacturers are responsible for the reporting of incidents. FIDE does not see a lack of clinical investigation data because the reference to clinical studies is a practical way if the devices are comparable. Additional FIDE pointed out that dental manufacturers include the question of the risk of products containing nanomaterials in their risk management.

j.) 3D Printing

FIDE is member in the EU-Commissions working group "New and Emerging Technologies". One of the subgroups is "3D Printing". In the last meeting the participants raised some questions which are important in conjunction with the new MDR. In Art. 2 Nr. 3 of the MDR the definitions are as follows:

"custom-made device means any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of this person's professional qualifications which gives, under his 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".

The following questions are open:

- Are 3D devices „custom made devices“ or „customized medical devices“?
- What is the definition of "industrial manufacturing"? Is the number of pieces essential?
- What is the classification of 3D printers?
- What is status of dental laboratories: Are they manufacturers with all legal obligations?

Dental manufacturers published the "position paper on dealing with custom-made devices according to MDR" in February 2018. The second paper is in preparation. It deals with the question of validation and quality management of custom-made devices. Goal is to publish this paper at the end of 2019.

V. Dental Stakeholder Conference

This meeting took place on 23rd February 2017 in Brussels. Participating associations were ADDE (dental dealer), CED (dentists), FEPPD (dental technicians) and FIDE (manufacturers). They discussed with members of the European Commission the implementation of the new Medical Device Regulation and the impacts for the dental sector. Other key aspect of the meeting was the debate on import of dental products into the EU, market surveillance activities and free movement of dental professionals. All organisations will keep contact and explore possible common initiatives of the dental sector as a whole.

VI. Market Data Survey

The annual ADDE/FIDE survey “European Dental Trade Survey (Market Trends)” is conducted through its national associations since 1998. Simon Gambold, Chairman of the FIDE Working Group Market Statistics, together with Dominique Deschietere, President of ADDE, have undertaken the supervision and completion of this valuable industry publication. In this joint effort, data submitted by the member associations of both ADDE and FIDE have been synthesized.

The survey represents the interests of more than 960 dental dealer organisations, covers the most relevant topics and trends for the European Dental Industry, such as the number of customers and end users, sales values for the main product categories, the use of computer and e-commerce, sales segments, distribution channels as well as VAT charges and their impact on the market.

The survey continues to be the most authoritative publication on the European dental industry. The cost of production has remained steady, allowing the 2019 version to be offered at the same price as in the previous years. More information, with a preview, is available on the ADDE website (www.adde.info).

VII. Fairs and Exhibitions

FIDE develops and publishes an overview about the worldwide most important dental fairs and exhibitions. This calendar will be continuously revised; it is available on the FIDE website.

VIII. International Representing of FIDE

As FIDE has no permanent establishment in Brussels, FIDE’s interests are represented by delegates, voluntarily placed at FIDE’s disposal from German member, VDDI, and Italian member association, UNIDI, ensuring continuity in the CEN TC 55 & ISO TC 106. In questions of standardisation and regulatory affairs, FIDE works successfully with other key European industry associations, notably through the long-standing cooperation with EUROM VI.

VDDI and UNIDI delegates are also permanent participants in the meetings of the MDEG (Medical Device Expert Group) at the EU-Commission in Brussels.

IX. FIDE Executive Committee

At the General Assembly in Cologne 2019, the slate of candidates was presented for election.

All candidates were unanimously elected for a two-year term of office.

The officers for 2019-2021 term are:

President: Gianfranco Berrutti (UNIDI, Italy)

Vice Presidents: Kim Soerensen (DBF, Denmark) and Olaf Sauerbier (VDDI, Germany)

Members: Peter Malata (FMWI, Austria), Nicolas Gehrig (ASDI, Switzerland), Juan Molina (FENIN, Spain) and Ian Pope (BDIA, UK).

X. FIDE MEMBERSHIP

FIDE represents the interests of more than 550 dental manufacturers affiliated to FIDE through their membership in national dental manufacturers associations in the European Union.

Current FIDE members include national manufacturers associations from the following countries:

Austria
Belgium
Denmark
France
Germany
Italy
The Netherlands
Spain
Switzerland
The United Kingdom

The next FIDE General Assembly will take place on Monday, March 08, 2021 in Cologne during the IDS. The Executive Committee will meet on the same day.

XI. FIDE-WEBSITE

More information about FIDE is available on our website

<http://fide-online.org>

XII. FIDE HEADQUARTERS

The General Secretariat of FIDE is located in the heart of Europe in Cologne, Germany through the auspices of its member association, VDDI. The FIDE headquarters team works in the interests of their member associations, carrying out the day-to-day business of FIDE and Executive Committee directives, in addition to the coordination and execution of liaison and logistical matters. The Secretariat maintains editorial responsibility for the Website and is also responsible for public relations.

FIDE
Federation of the European Dental Industry
Aachener Strasse 1053-1055
50858 Cologne
GERMANY
TEL: +49 (221) 500 687 0
FAX: +49 (221) 500 687 21
EMAIL: info@fide-online.org
Web: www.fide-online.org

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