

Articles of Association as of 07/12/2016

OR.NET

Preamble:

The increasing number of computer-assisted devices and instruments has led to the current need to integrate medical systems and software solutions into a comprehensive infrastructure in operating rooms and clinics. The large variety of devices and the information that accompanies them can be integrated into new and innovative functions within the framework of this network through dynamic networking and convergence. The overriding goal of technical developments in medicine should be to improve the quality and safety of healthcare. The security and usability of networked medical devices and IT systems present a key quality criterion and an element of risk management. Due to increasingly complex technology and the growing complexity of human-machine interaction in medical environments, this aspect is becoming increasingly important in the risk management of medical products.

The goal of OR.NET is, based upon the results of the BMBF project OR.NET (2012-2016) in the pre-competitive field of medical and technical research and development, to further develop and evaluate fundamental concepts for the secure dynamic networking of components in the operating rooms and clinics, to transfer them into standardized activities, to portray them in specially designed training course and service offerings in connection with testing and approval, thereby also securing and expanding their sustainability. In particular, the automatic dynamic networking of computer-controlled medical devices among themselves in the operating theatre and their interaction with medically approved software present particular challenges to Information and Communication Technologies (ICT) in the medical application environment. Thanks to the open networking based on a standardization of technical interfaces, innovative solutions can be created for more effective and efficient operative and intensive medical care. At the same time, quality assurance and standardization of clinical workflows at the expert level can be technically supported. Through long-term collaboration between clinical users, operators, manufacturers, science and regulating bodies, new ways to design software architectures and medical device IT systems in the hospitals of the future can be developed. In addition to medical technology and IT in operating rooms and adjacent areas, connected systems for operation planning, monitoring, diagnosis and therapy, as well as for pre-, intra- and postoperative intensive medical care must also be taken into consideration. The infrastructure's networking, interoperability and safe operation are top priorities. The collaboration between science, clinics and business must be intensified and focused on the important area of innovation in medical devices and medical software in a targeted and application-oriented manner. Measures in the areas of clinical and technical research and development, standardization, quality assurance and risk management must be coordinated and accelerated. These include the areas of education and training

for both clinical users as well as technical personnel for development, operation and maintenance as well as verification, validation and approval of modular networked systems. In this context, the structure, development and operation of test laboratories, simulators and demonstration systems for partial aspects, components and overall systems are also important.

The operational basis of the collaboration is to form working groups in which different topics are dealt with in the context of the association's goals, and which are interlinked by a regular exchange of information.

Potential topics of the working groups could be, *inter alia*:

- Approval and certification ("OR.NET approved/certified")
- Data model, BICEPS, standardization
- Usability
- Libraries (OSCLib and OPENSDC)
- Internationalization
- Test systems, strategies and simulators
- Networking of distributed and cooperating "OR.NET test centers" and demonstrator sites where local operators are OR.NET members.

§1 Name, Location, Fiscal Year

1.1 The association is named "OR.NET" and pursues exclusively non-profit purposes.

1.2 The association's registered location is in Aachen.

1.3 The association shall be registered in the association register of the District Court of Aachen; after the entry, it shall bear the addition "e.V."

1.4 The fiscal year is the calendar year.

§ 2 Purpose

2.1 The association is intended to advance public healthcare. It promotes quality and safety in healthcare by independently researching, developing, providing, publishing and applying procedures, methods and tools for the development, provision, placement, training and use of procedures, methods and tools for the manufacturing and testing, operation and application of technical solutions and products, components, modules and systems for the secure and dynamic networking of operating rooms and clinics. This includes technological (further) developments and services to improve medical device and

information technology systems, work processes and organizational structures as well as measures for the international standardization and dissemination of appropriate solutions.

2.2 The purpose of the Articles of Association shall be achieved in particular by:

- Promotion of the acquisition of knowledge in the fields of information technology and medical technology, as well as risk management and the clinical usability of modularly networkable medical device IT solutions with regard to their integration into medical or medical technology work and application processes,
- Identifying the need for research as well as funding, initiating, and supporting research projects in the abovementioned areas,
- Research and development and/or application of procedures, methods and tools for the verification, validation, and approval of modular networkable systems,
- Development of guidelines, checklists, and standard operating procedures for the implementation and use of networked systems
- Independent testing of medical devices and IT systems, in particular regarding aspects of technical safety and usability,
- Development, support, and promotion and operation of programs and facilities for
 - Clinical education and training, e.g. integrated learning environments for doctors, operating staff, students
 - Technical education and training: Integrated learning environment for clinical risk managers, information and medical technicians
 - Technical certification and testing: Development platform and test centers for software and hardware components and systems
 - Validation and research: Further development and validation of tools, device profiles, user interface profiles, including manufacturer-wide interaction-based evaluations in test scenarios
 - Consulting on the implementation, testing and use of networked systems
- Long-term maintenance and further development of the OR.NET standard
- Exchange of data and information, including free tools
- Submitting applications for funding for joint research projects or other research projects,
- Support in the development and implementation of joint projects and support and implementation of meetings, workshops, symposia, trainings, and other appropriate measures to sustainably promote the transfer of knowledge between scientists, industry, and medicine, support consultation for developers, manufacturers, operators, and users, as well as the establishment of healthcare facilities in general in developing, licensing, manufacturing, and implementing appropriate technologies, as well as in the search for potentially suitable service partners,
- Granting aid for the printing of scientific papers, bibliographies, work manuals, and brochures
- Promotion of international specialist lectures, colloquiums, training events, specialized

exhibitions, trade fairs, and external studies in the abovementioned areas,

- Granting of scholarships to especially gifted and in need students and doctoral students,
- Constructive cooperation with national and international organizations and associations as well as the exchange of information and cooperation with experts in Germany and abroad,
- Publicity work for the dissemination of the association's goals and thematic content in the abovementioned areas
- Measures for education and training, as well as measures for the sustained promotion of knowledge transfer and contact management between science and industry, as well as clinical users, public health care institutions and authorities.
- Creation of information and communication platforms on topics relevant to the objectives of the association.

2.3 All findings and results obtained within the scope of the activities of the association shall be made available in publications to the members of the association and to the general public in a timely manner.

2.4 In order to pursue its objectives, the association may, for its part, acquire membership in other charitable organizations.

2.5 The association may establish its own corporations and participate in other corporations.

2.6 In order to achieve its statutory purposes, the association may employ auxiliary staff within the meaning of section 57 (1) Sentence 2 of the German Tax Code (AO). This applies in particular to the allocation of research contracts.

§ 3 Non-profit Status

3.1 The association exclusively and directly pursues non-profit purposes within the meaning of the "Tax Beneficiary Purposes" section 52 of the German Tax Code (AO) and has the right to issue donation certificates for tax purposes (Annex 7 to Section 111 of the German Income Tax Regulations [EStR]). The association works selflessly; it does not primarily pursue individual economic purposes.

3.2 The association's funds may only be used for statutory purposes. The members do not receive any profit shares and, in their capacity as members, do not receive any other contributions from the association's funds. The association does not favor persons by means of administrative expenses or disproportionately high remuneration. The members have no right to claim on capital shares or contributions in kind or their value when they leave the association or when the association is dissolved or abolished.

3.3 In the case of the dissolution or abolition of the association or in the event of the

abolition of a tax-privileged purpose, the assets of the association shall be transferred to the Caritas Association of the Diocese of Aachen (Caritas-Verband der Diözese Aachen e.V.), which shall use it directly and exclusively for charitable purposes.

§ 4 Membership

4.1 The association has full, associate and sponsoring members.

4.2 Legal entities of public and private law as well as research groups and associations of persons, such as associations, unions, etc., whose activities cover the areas referred to in § 2, may be accepted as full and associate members.

4.3 Full and associated members have the right to,

- Active participation and decision-making in the organs of the association, as well as the submission of proposals on the agenda of the General Meeting and proposals for the formation of working groups
- Active participation in working groups
- Access the protected area of the web-based coordination and information exchange platform with software tools, work packages and other information

4.4 Full members also have

- The right to be the main applicant for research and development projects funded through OR.NET and thus have a decisive influence on the definition of research questions and the development of common technological solutions,
- The right to stand for election

4.5 Further rights and duties of the full and associate members are regulated in the rules of procedure of the association committees.

4.6 Sponsoring members may be legal and natural persons who support the association financially through regular contributions. The conditions applicable to full or associate members do not need to be met. Sponsoring members do not have voting rights, nor are they eligible to stand for election. They do not have the rights mentioned in § 4.3 and § 4.4.

4.7 Each member shall appoint a representative to represent it with the association. A representation of several members by one and the same person is not permissible.

4.8 The association shall charge a one-time initiation fee and an annual contribution, which shall be paid in advance for the calendar year. The amount of the initiation fee and the annual contribution is set out in the contribution schedule. The General Meeting

decides on the contribution rules.

4.9 Any activity remuneration to members of the association (for example, for office work, training and education activities, or research or advising third parties) who are not also on the Executive Board shall be admissible if this has been approved by the Executive Board.

4.10 Members may be granted special conditions for the use of the association's proprietary hardware, software, infrastructure, and service offerings, participation in education, training, and information exchange activities, provided that the benefits to public healthcare outweigh the advantages gained by the individual members. Members of the association may also be granted study or research assignments that serve the purposes of the association. The prerequisite for this is that these services would otherwise have to be provided at comparable conditions by non-members.

§ 5 Acquisition of Membership

5.1 The application for admission to the association must be addressed in writing to the Executive Board, which decides on admission or rejection. In the case of refusal, the applicant may lodge a written complaint within one month after receipt, which shall be decided by the next meeting. There is no right to membership.

5.2. The admission on the basis of a positive decision of the Executive Board becomes effective only after payment of a subscription fee and the first annual contribution as established in the contribution regulation.

5.3 Members joining during the current year must pay the full annual membership fee.

5.4. Confidentiality within the framework of collaboration in the association

In order to promote trustworthy collaboration within the meaning of the association's objectives, the exchange of otherwise confidential information between members is to be simplified. Since, from experience, a binding agreement for the confidential treatment of written information, marked as "confidential", promotes this collaboration in the sense of the association's purpose, the following regulations shall apply:

5.4.1 By acquiring the membership, each member agrees to treat with confidentiality the information to be disclosed or made available to them in the framework of collaboration with members of the association that are marked as "confidential", and to only provide such information to third parties with the consent of the person who confers said confidential information. This also applies to information from third parties which is made accessible by the other partners in the context of the collaboration.

5.4.2 The obligation to maintain confidentiality shall not apply to information which:

- is generally known through publications or the like, or
- becomes part of the public domain without fault of the receiving partner, or
- has been transferred to a partner by a third party without a confidentiality obligation, or
- was already known to the receiving partner before notification by another partner, or
- is the result of the work of employees of the receiving partner, without the respective employees having access to the information, or
- must be disclosed on the basis of an official or court order.

5.4.3 Members shall obligate the staff involved in the project to protect confidential information.

5.4.4 The obligation to maintain confidentiality shall continue beyond the membership for a period of three years after the end of the membership.

5.4.5 Members undertake to mutually coordinate on publications which impact confidentiality and not to unreasonably refuse approval for publication in the sense of the objective of §2.

§ 6 Termination of Membership

6.1 Membership ceases upon

- Resignation of the member,
- Expulsion of the member or
- Death of the member or dissolution of the legal entity.

6.2 Termination of membership does not release the member from any remaining obligations to the association.

§ 7 Resignation

Voluntary resignation is made by a written statement submitted to a member of the Executive Board. Resignation is only permitted at the end of a calendar year subject to a notice period of three months.

§ 8 Expulsion

8.1 The Executive Board may decide to expel a member for breach of essential membership obligations or other serious reasons. The decision shall be justified and made known to the member. The member may object to the expulsion within one month. The General Meeting shall decide on this objection. Pending the decision on the effect of the exclusion, the membership rights of the excluded member shall be suspended.

8.2 Serious reasons include, *inter alia*:

- Gross violation of the statutes of the association, resolutions or orders of the association bodies or the association's internal peace,
- Damage to the reputation or interests of the association,
- Non-timely payment of the membership fee, despite prompts.

§ 9 Formation of Working Groups

9.1 In order to process certain tasks, members of the association may, with the consent of the Executive Board, form working groups within the association. The working groups may be formed by full and associate members. Each working group must have at least two full members.

9.2 The working groups may have their own rules of procedure. These may not be contrary to the statutes of the association and require the approval of the Executive Board.

9.3 The working groups do not have their own legal personality.

9.4 The General Meeting may terminate the working groups by resolution.

§ 10 Formation of an Advisory Board

10.1 An Advisory Board may be set up to assist the Executive Board.

10.2 The members of the Advisory Board shall be appointed by the Executive Board for a limited period and shall be experts, e.g. with regard to the areas referred to in section 2.

They originate in particular from

- Public health institutions,
- Medical companies,
- Science and Research,
- Trade associations and funding agencies.

10.3 The activities of the Advisory Board may be regulated in a set of rules of procedure, which the Executive Board determines. The rules of procedure must not be contrary to the statutes of the association.

10.4 The Advisory Board does not have its own legal personality

10.5 The members of the Advisory Board do not need to be a member of the association.

§ 11 Executive Bodies

The association's executive bodies are:

- The Executive Board and
- The General Meeting.

§ 12 Executive Board

12.1 The voluntary Executive Board consists at least of the chairperson and their deputy as well as the treasurer.

12.2 The chairperson of the Executive Board and the deputy chairperson and the treasurer as well as any other members of the Executive Board are elected by the General Meeting for a period of three years. Upon request of a member, the election must be conducted in writing and confidentially. Re-election is permitted. The Executive Board remains in office until a new election.

12.3 If a member of the Executive Board withdraws prematurely, a new member of the Executive Board is elected for the remainder of the term of office by the General Meeting. Until then, the remaining members of the Executive Board shall appoint a substitute member. This also applies if a member of the Executive Board cannot perform their duties for more than six months.

12.4 The General Meeting may decide that members of the Executive Board will be paid for the benefit of the association on the basis of a service contract, a project grant or a flat-rate compensation.

12.5 In addition, the members of the Executive Board have a right to claim compensation according to § 670 German Civil Code (BGB) for expenses incurred by them for their activities for the association. This includes, in particular, travel, telephone, photocopying, printing, and postage costs.

§ 13 Powers of the Executive Board

On behalf of the General Meeting, the Executive Board is responsible for ensuring the adherence to the association's goals, for ensuring that the resolutions passed by the General Meeting are taken, and for overseeing all matters of the association and representing and promoting its interests. It performs its rights and duties, carries out the daily business, and is entitled to conclude and terminate all contracts. It manages the financial and asset management of the association. It decides on all matters, unless they are reserved for the General Meeting.

§ 14 Head Office, Managing Director

14.1. The chairperson of the Executive Board is entitled to set up a main office and to appoint a full or part-time director to carry out the business of the association, in particular the ongoing administrative activities. This may be one of the members of the Executive Board as referred to in § 12.1, and in this case, both offices are to be undertaken simultaneously. The chairperson of the Executive Board is the chief executive of the managing director and is also entitled to dismiss the latter. The regulations in § 4 and § 12 apply to a possible remuneration of the management activities. As regards third parties, the managing director may only conclude legal transactions for the association together with the chairperson or deputy chairperson. The managing director is solely authorized to conclude legal transactions that do not charge the association more than EUR 10,000.00.

14.2 The following shall apply internally: The appointment and dismissal of the managing director by the chairperson of the Executive Board is carried out by a decision issued by the Executive Board.

14.3 If a managing director is appointed, he or she shall be invited to the meetings of the Management Board. However, from the office as managing director, there is no voting right in the Executive Board.

14.4 The following shall apply internally: If a managing director has been appointed, he or she shall assume his or her duties in consultation with the treasurer.

14.5 The functioning of the managing director is governed by the rules of procedure.

14.6 Upon request, each managing director shall be given the necessary power of attorney.

§ 15 Representation of the Association

15.1 The association shall be represented by the chairperson or the deputy chairperson and a further Board member.

15.2 The chairperson and the deputy chairperson alone are entitled to conclude legal transactions which do not charge the association more than EUR 10,000.00.

15.3 The following shall apply internally: The deputy chairperson shall only act in the event that the chairperson is prevented from doing so.

15.4 The chairperson of the Executive Board may grant a power of attorney to another member of the Executive Board, also to a third party, to publicly issue the corresponding declarations on Executive Board resolutions. The chairperson of the Executive Board can only issue a revocable power of attorney, unless the power of attorney is limited to a specific individual transaction.

§ 16 Rules of Procedure of the Executive Board

16.1 The Executive Board is convened by the chairperson in writing (where applicable by fax or read-receipt email). The Executive Board is quorate if more than half of its members are present. Decisions shall be taken by a simple majority of the votes of the members present; in a tie vote, the chairperson shall decide. The Executive Board must be convened if at least two of its members require it.

16.2 A written record must be included that contains the decisions taken. It must be signed by the meeting leader and the recording clerk. The memorandum will be sent to members of the Executive Board as soon as possible, but within a period of two weeks in writing (where applicable by fax or read-receipt email). The minutes shall be deemed approved if no objection is lodged with the chairperson or the secretary within one month after receipt in writing (where applicable by fax or email). In the event of a conflict, this shall be presented at the next meeting of the Executive Board.

16.3 The meetings and resolutions of the Executive Board may also be carried out and taken using electronic means of communication.

16.4 The Executive Board also regulates its own procedures.

§ 17 The Convocation of the General Meeting

17.1 The Executive Board shall convene a regular General Meeting at least once a year, to which the full and associate members shall be invited at least four weeks in advance. The invitation shall be made in writing (where applicable by fax or read-receipt email). The agenda will be included in this communication. The General Meeting will adjudicate the final agenda.

17.2 Any full or associate member may submit proposals to the General Meeting. These must have been sent to the Executive Board up to 14 days before the meeting in writing (where applicable by fax or read-receipt email). The General Meeting decides on the admission of applications.

17.3 An Extraordinary General Meeting shall be convened upon written request (where applicable by fax or read-receipt email), stating the agenda of at least 40% of the members. For the formal procedure for the convening of an Extraordinary General Meeting, the rules for the convening of ordinary general meetings shall apply accordingly.

17.4 The General Meeting shall be chaired by the chairperson of the Executive Board, and in the event of a hindrance by his or her representative.

17.5 A written record must be included that contains the decisions taken. It must be signed by the meeting leader and the recording clerk. The recording clerk will be proposed by the assembly leader at the beginning of a meeting and elected by the General Assembly. The memorandum will be sent to the members in writing as early as possible, but no later than within one month (by fax or by read-receipt email). The minutes are deemed to be approved if the Executive Board does not object to them in writing within one month after receipt (where applicable by fax or read-receipt email). In the event of a conflict, this must be submitted at the next annual meeting.

17.6 The General Meeting may also occur via telephone, video or web conference; the access data must be sent to all members in writing at the latest one week before the meeting (by fax or by read-receipt email). The remaining provisions 17.1-17.5 shall apply accordingly in this case.

§ 18 The Tasks of the General Meeting

18.1 The General Meeting elects the Executive Board and the auditors. It accepts the

annual report of the Executive Board and the financial statements.

18.2 The General Meeting decides on:

- The dismissal of the members of the Executive Board,
- Remuneration for the Executive Board
- The contribution schedule and the admission fee,
- The decision on the acquisition of membership of third associations,
- The amendment of the Articles of Association,
- The dissolution of the association

18.3 The General Meeting shall be quorate without regard to the number of voters who are entitled to vote if it is duly convened. A resolution shall be taken by a simple majority of the members who are entitled to vote; abstentions are not included in the determination of the results of the voting.

18.4 Amendments to the Articles of Association and the dissolution of the association require a majority of three quarters of the voting members present. In these cases, a written vote is required. The Executive Board is entitled to resolve amendments to the Articles of Association, which are necessary due to official or judicial complaints or due to amended legal provisions. The members are to be notified immediately in writing of any changes.

18.5 Full and associate members have a simple active right to vote in the General Meeting.

18.6 Roll-call votes (including elections) of the members may be carried out by telephone or in text form by email or other electronic voting methods (for example <https://terminplaner.dfn.de/> or <http://doodle.com/>). The access data will be sent to all members in writing by the Executive Board (where applicable by fax or read-receipt email) no later than 2 weeks before the final deadline of the vote. The names of the votes must be communicated to all members in writing after completion of the vote (where applicable by fax or read-receipt email). The voting results shall be valid if the personal voting result mentioned above is not objected to by the Executive Board within one month after notification in writing (where applicable by fax or read-receipt email). The remaining provisions 18.1-18.5 shall apply accordingly in this case.

§ 19 Auditors

19.1 The General Meeting shall elect two full members as auditors for a period of three years. Re-election is permitted.

19.2 The auditors shall examine the annual accounts. Intermediate and individual tests can be carried out. They report on the results at the General Meeting, which is to decide on the discharge of the members of the Executive Board.

19.3 The auditors do not have seats and votes on the Executive Board. They may participate in meetings of the Executive Board upon invitation.

§ 20 Liability

The assets of the association are solely liable for the liabilities assumed by the association. Liability of the individual members of the association or of the Executive Board on the basis of their association or membership of the Board is excluded, unless compelling legal regulations stipulate otherwise.

§ 21 Dissolution

The dissolution of the association may be decided at a General Meeting with the majority of the votes cast in as stipulated in § 17. Unless the General Meeting decides otherwise, the chairperson and the deputy chairperson shall be jointly authorized liquidators. The foregoing provisions shall apply mutatis mutandis in the event that the association is dissolved for another reason or loses its legal capacity.

§ 22 Date of incorporation

The Articles of Association were adopted in the 02/03/2016 version at the inaugural meeting on 02/03/2016.