SPONSORSHIP AGREEMENT FOR CME EVENT (SPONSOR - PROVIDER)

CONFINDUSTRIA
Dispositivi Medici

This Sponsorship Agreement for a CME event (hereinafter "**Agreement"**) is entered into

BETWEEN

[***] ***[Name of the sponsoring company]***, with registered office in [***], fiscal code and VAT number [***], registered with the register of enterprises of [***], under number [***], hereby represented by its legal representative pro tempore [***], (hereinafter th "**Company**" or "**Sponsor**")

AND

[***] [***Name of Provider***], with registered office in [***], VAT No. [***], Agenas No. [***], hereby represented by its legal representative [***], with the necessary powers (hereinafter, "**Provider**")
Hereinafter also referred to jointly as the "**Parties**" and individually each as the "**Party**".

WHEREAS

I. the Company carries out its activity in the field of research, development, promotion and commercialization of medical technologies;
II. the Company actively supports initiatives for independent medical training on leading clinical, scientific and health issues in the therapeutic areas of interest to the Company or in which it is involved;
III. the Provider is a qualified subject in the field of Continuing Medical Education (CME) and qualified to carry out CME training activities, also by awarding training credits to participants;
IV. the Provider, in full compliance with all legislations on congresses and conferences and, among other things, with the State-Regions Agreement of 2 February 2017 with which the Government, the Regions and the Autonomous Provinces of Trento and Bolzano approved the document "Continuing Education in the Health Sector" and with the National Accreditation Manual for the Delivery of CME Events (hereinafter "**CME Regulations**") intends to hold a CME Event aimed at the professional updating of specialized doctors, entitled [***] to be held in [***] on [***], better described under Annex 1 (hereinafter "Event");
V. the Provider, in compliance with the CME Regulations, with art. 124 of Legislative Decree 24 April 2006, where applicable, as well as with the principles set forth in the MedTech Europe Code of Business Practice ***[NOTE: delete where not applicable]*** and in the Confindustria Dispositivi Medici Code of Conduct, intends to acquire sponsorships for the purpose of carrying out the Event and has submitted to the Company, for this purpose, the programme of the Event;
VI. the Company has examined the programme and found that the educational and training activity to which the Event is directed is aimed exclusively at the development of scientific knowledge and technical-professional skills in the healthcare sector, and is therefore objective and independent, and has declared to be willing to support the same under the terms and conditions of this Agreement;
VII. The Parties, for the purposes of this Agreement, act as independent contractors, not bound by any *affectio societatis*, nor any corporate bond, connection or control

NOW, THEREFORE

the Parties thereby agree and stipulate as follows:

1. Subject of the Agreement

1.1 The subject of this Agreement is the sponsorship of the Event by the Company.

1.2 The Provider undertake to organise the Event in full compliance with all applicable legislations, such as, *inter alia*, the CME Regulations, art. 124 of Legislative Decree 219/2006 (as applicable), art. 53 of Legislative Decree 165/2001, as well as the principles set forth in the MedTech Europe Code of Business Practice ***[NOTE: delete where not applicable]***, adopting the rules of fairness and transparency, without suffering interferences by the Company, and declare to carry out their activities in the absence of any conflict of interest. The procurement of all the resources and means necessary to guarantee the success of the Event is the responsibility of the Provider. It is understood that the funds necessary for the realisation of the Event may also be collected by the Provider through other sponsors.

1.3 The Company, for its part, undertakes to support the organisation of the Event in accordance with the provisions of art. 2 below, while the Provider assume the obligation to spread the name/brand of the Company within the limits set forth in the following articles, as well as the further obligations set forth in art. 2.

1.4 The Provider is responsible for the organisation of the Event and the training content, scientific and didactic quality, as well as the ethical integrity of all the educational and training activities that will be carried out at the Event.

1.5 For the purposes of this Agreement, the Provider designates Prof. [***] (hereinafter "**Scientific Coordinator**") as the Scientific Coordinator for the Event.

1.6 The Provider declares that the Event has been organised in collaboration with the Scientific Coordinator and will be conducted in full autonomy and without any influence or interference. It is, in fact, in the Parties" interest to provide learners with training activities conducted with professionalism and scientific rigour and with the utmost independence, since the aims of the Event are and shall remain solely those of education and training.

1.7 In order to allow verification of the quality and scientific objectivity of the Event, the Provider declares as of now that a specific questionnaire will be submitted to lecturers and trainees in which they may express their comments, indicating, among other things, whether they perceived a conflict of interest in the material distributed or in the management of the Event itself. The Provider declares and guarantees that the Scientific Coordinator and the lecturers involved in the conception and realisation of the Event will not derive any advantage from the sponsorship of the Event by the Company or, in any case, from the signing of this Agreement.

1.8 The Provider declares and guarantees that the contributions collected for the purpose of sponsoring the Event will be used exclusively for the organisation of the Event and will not be used in any way for:

a) the direct or indirect promotion of the Company"s products or services;

b) the payment of exhibition costs for the promotion of its services;

c) the support of charitable programmes;

d) covering overall organisational costs, such as the purchase of capital goods, software and training of non-medical personnel.

1.9 The Provider undertakes to provide the Company, at least 75 (seventy-five) days before the beginning of the Event, with the programme, the documentation and all the information necessary to proceed with the request for authorisation to AIFA (Italian Medicines Agency) envisaged by Article 124 of Legislative Decree No. 219/06. In any event, the final programme of the Event must be submitted at least 15 (fifteen) days before the date on which it is to be held. The Provider shall directly pay and/or reimburse the Company for any additional registration and/or authorisation fees or costs and expenses relating to the procedure with AIFA pursuant to Art. 124 of Legislative Decree no. 219/2006, the payment of which is directly or indirectly determined by and/or attributable to the error, fault or negligence of the Provider or of any other party used by them in relation to the aforesaid procedure. ***[NOTE: delete where not applicable].***

1.10 Finally, the Provider also undertakes to:

a) pay the CME contribution to the National Agency for Regional Health Services (AGENAS);

b) include the Event in the calendar of events on its website or use other means and tools to publicise the event;

c) send the Event programme;

d) convey and display the Company"s name and logo, in compliance with the CME Regulations;

e) keep complete and accurate records of its relationship with the Company for a period of no less than 5 (five) years.

2. *[OPTION 1: select in the event that the sponsorship consists of the provision of a non-conditional financial contribution]* Sponsorship Contribution

2.1 Subject to the terms and conditions set out in this Agreement, the Company agrees to grant to the Provider for the realization of the Event the amount of [***] (hereinafter "**Contribution**").

2.2 Payment of the Contribution shall be made by the Company within [***] days from the signing of this Agreement by all the Parties, and in any case after such date, within [***] days of the end of the month invoice date, by payment to the following account number

Account Holder: [***]
Banking Institute: [***]
IBAN Code: [***]
BIC Code: [***]

2.3 In consideration of the aforesaid contribution, the Provider undertakes to make available to the Sponsor an exhibition space of ***[specify details regarding the exhibition space]*** for the display and illustration, by qualified personnel authorised by the Company, of the technical and scientific characteristics of the products falling within the product sector pertaining to the Event (hereinafter, **"Exhibition Space"**).

The Provider also undertakes to allow personnel authorised by the Company access to the Stand Space also outside the hours of the Event for practical-organisational purposes ***[NOTE: delete the paragraph where not applicable and replace with the appropriate details].***

2. *[OPTION 2: select if sponsorship consists in the supply of products and/or equipment]* Sponsorship

2.1 Subject to the terms and conditions set out in this Agreement, the Company agrees to deliver to the Provider only such products/equipment as may be necessary for the purpose of carrying out the Event, consisting of *[insert number of products/equipment and description]* (hereinafter, the "**Devices**"). The Provider shall not transfer or assign the Devices provided by the Company to third parties.

2.2 The Company undertakes, at its own care and expense, to deliver the Devices to the Event location one day before the beginning of the Event.

2.3 The Provider declares and guarantees that the Devices shall be used exclusively during the Event and to carry out the planned training activities, in accordance with the relative instructions for use and the instructions received from the Company.

2.4 At the end of the Event, the Company, or its appointee, undertake to fully collect the Devices not used during the Event. The Provider undertakes to cooperate with the Company or its appointee to enable the collection of the Devices.

2.5 The Provider declares and guarantees that the Devices will be used during the Event in such a way that the Company/product brand does not appear and will be identified during the Event exclusively by their generic name, and in such a way that the Company brand or sign cannot be perceived by those present.

2.6 For tax purposes, it is acknowledged that the value of the Devices is € _____.

3. Ethics and Compliance

3.1 The Company, a member of Confindustria Dispositivi Medici, may only provide its support to events of a national, regional or inter-regional nature which have been submitted by the Provider to the Conference Vetting System (CVS) of Confindustria Dispositivi Medici or to events of an international nature which have been submitted by the Provider to the Conference Vetting System (CVS) of MedTech and which have been positively evaluated.

3.2 The Provider declares and guarantees that whatever is received by way of support for the organisation of the Event shall be used in compliance with the provisions of the MedTech Europe Code of Business Practice ***[NOTE: delete where not applicable]***, the Confindustria Dispositivi Medici Code of Conduct and any other national laws and regulations, including CME Regulations.

3.3 The Parties expressly agree that the support received pursuant to this Agreement shall in no way, either implicitly or explicitly, create an obligation on the part of the Provider to purchase, rent, recommend, prescribe, use, supply or purchase for other parties, the services and products bearing the Company"s brand name, nor shall it reward previous purchases, uses, orders or recommendations.

4. Independent Selection

4.1 The Company shall in no way be involved in the selection of healthcare professionals to attend the Event and the Provider shall be solely responsible for the selection of participants.

4.2 The Provider shall be solely responsible for:

(i) the content of the programme

(ii) the selection of the speakers, moderators and/or panelists who will speak during the Event (hereinafter, "**Faculty**")

(iii) the payment, where required, of the remuneration due to the members of the Faculty.

4.3 The Company shall not be involved in any way in deciding the content of the training programme nor in the selection of the Faculty. If expressly requested by the Provider, the Company may provide, at the conclusion of the Event, evaluations on the content of the programme.

4.4 Finally, it is understood between the Parties that the list and addresses of participants in the Event shall be kept confidential and shall not be transmitted to the Company or used for commercial purposes in any way. However, only the total number of learners attending the Training Event may be communicated to the Company.

5. Conflict of Interest between Provider and Company

5.1 In order to prevent the occurrence of situations of conflict of interest, and in compliance with the provisions of the CME Regulations, the Parties acknowledge that

a) no compensation will be provided by the Company directly to the Event"s Scientific Coordinator, to individual lecturers or to other parties involved in the Event;

b) the Provider will acquire the necessary statements regarding the Scientific Coordinator"s and the lecturers" past relations with subjects with commercial interests, who might benefit from the educational activities

c) the planning and delivery of training activities, as well as the production of educational material, are managed solely by the Provider. The Company shall not and cannot in any way influence the planning of the content or the conduct of the educational activity it sponsors;

d) the Company, in the course of the execution of this Agreement, may not subordinate the payment of the Contribution/Delivery of the Devices **[NOTE: select applicable option]** to directives or advice concerning the content, the teaching staff or other matters relating to the normal running of the Educational Event;

e) the Provider may authorise the Company to disseminate information regarding the CME activity to the community of healthcare professionals. Any such information, however, must be agreed upon in advance with the Provider and must highlight that the CME activity is carried out by the Provider with the non-conditional support of the Company;

f) the Provider will collect applications from participants in the training Event without interference from the Company, guaranteeing the confidentiality of the lists, names and addresses of participants, which may not be transmitted to the Company or used, in any case, for commercial purposes;

g) the Provider, during the course of the Event, will invite participants to fill in a specific questionnaire in which they will be able to indicate whether they have perceived any commercial influence during the course of the training activity;

h) no promotional material will be displayed or distributed in the same room where the training activity takes place. The Company, therefore, during the Event will have its own exhibition spaces in separate rooms from those of the classrooms dedicated to training, agreed with the Provider;

i) the printed material, in the pages dedicated to CME activities, in the adjacent pages or within related tools (for example, pages dedicated to the evaluation of learning) will not bear any form of publicity or reference to the Company;

j) it is permitted to indicate the name and logo of the Company on the last page of brochures, CME activity programmes and information material, as well as before the beginning and after the end of the Event. Under no circumstances may reference be made to the commercial name of products of health interest during the Event and in the spaces dedicated to training

6. Verifications and Controls

6.1 At the Company"s request, the Provider shall provide the Company with a report on the use of the Contribution/Devices ***[NOTE: select applicable option]*** and/or appropriate documentation proving such use under the terms and conditions set forth in this Agreement.

7. Duration and Resolution

7.1 This Agreement will be effective from the date of execution (hereinafter "**Effective Date**") and will remain in force until the conclusion of the Event or its cancellation, without prejudice to the application of provisions which by their nature are intended to survive the termination of this Agreement.

7.2 The Company will have the right to terminate this Agreement by written communication sent to the Provider via PEC or registered letter, pursuant to and for the purposes of art. 1454 of the Italian Civil Code, in case of serious default on the part of the Provider which is not remedied within a period of three (15) days from the date of receipt of the relevant warning to comply. In such case, the Company shall be entitled to the immediate refund of the Contribution not yet used on the date of termination of this Agreement, with obligation for the Provider to provide a detailed account of the portion of Contribution used. ***[NOTE: in case of delivery of Devices replace with "In such case, where applicable, the Company shall be entitled to the immediate return of the Devices at the expense of the Provider according to the instructions given by the Company"]***

7.3 The Company will also be entitled to terminate this Agreement with immediate effect, by written notice sent to the Provider via PEC or registered letter, pursuant to and for the purposes of art. 1456 of the Italian Civil Code, when expressly provided for in this Agreement. For the purposes of returning the Contribution and/or the Devices ***[NOTE: select applicable option]***, the provisions of art. 8.2 shall apply.

7.4 In case of non-approval of the event by the MedTech Conference Vetting System or SVC of Confindustria Dispositivi Medici, where required, or declaration of non-conformity of the Event with the provisions of the Code of Ethics of MedTech Europe or Confindustria Medical Devices, this Agreement shall be considered as never concluded and without effect, with the obligation for the Provider to arrange for the immediate return of the Contribution and/or the Devices ***[NOTE: select applicable option]*** to the Company, no later than 3 working days from the relevant request, where applicable.

7.5 If the Provider is revoked or suspended for any reason from holding CME events during the term of this Agreement, it will be automatically terminated, with return to the Company of the Contribution/Devices already delivered and not yet used ***[NOTE: select applicable option]***, without prejudice to the right to compensation for damage suffered by the latter if the withdrawal of accreditation is due to a fact attributable to the Provider.

7.6 If the Event is not held due to an event of force majeure, the Company will be entitled to the refund of the Contribution and/or will not be required to pay it, as applicable, without prejudice to the share to cover the expenses incurred by the Provider in relation to which due evidence is provided to the Company, taking into account, where appropriate, also the contributions made by other sponsors. ***[NOTE: in case of delivery of Devices replace with "the Company, or its representative, will immediately proceed to the withdrawal of the Devices"].***

8. Code of Ethics and Legislative Decree 231/2001

8.1 The Provider shall comply and cause its personnel to comply with the Code of Conduct available on the website of the Company at page [***] as well as the principles ex D. lgs. 231/2001. The violation of the rules provided for in this document and by D. lgs. 231/2001 will constitute serious breach of this agreement. The Provider undertakes to indemnify the Company from now on for any penalties or damages that may arise as a result of the violation of the aforementioned Code of Conduct and D. lgs. 231/2001 by the Provider or its own staff.

8.2 The Provider also undertakes to report to the Supervisory Body, at [***], cases of violations of the Code of Conduct of the Company as well as in case of commission of the offences provided for by D. Lgs. 231/2001.

9. Processing of personal data

9.1 The Parties declare that they act as autonomous controllers in relation to the processing of personal data by them carried out during the execution of this Agreement. In particular, the Provider declares and guarantees that personal data relating to their employees and collaborators, as well as to participants in the Event (hereinafter "personal data"), will be processed in full compliance with Regulation (EU) 2016/679 ("GDPR") and the applicable national legislation (D.Lgs. 101/2018 and Measures of the Garante).

10. Transparency Obligations

10.1 The Provider declares that it is aware of the fact that the Company adheres to Confindustria Medical Devices and its Code of Ethics and is therefore subject to the obligation to document and make public the transfers of value made directly or indirectly towards health professionals, health organisations and third parties, in accordance with para 4 of the Code of Ethics for Medical Devices, available here: https://www.confindustriadm.it/codice-etico/.

The transparency obligations mentioned above will automatically lapse when the public telematic register called "Sanità Trasparente" of the Law n. 62 of 31 May 2022 (the so-called "Sunshine Act") comes into operation.

In fact, in view of the implementation of Law n. 62/2022 (the so-called "Sunshine Act"), the Provider is committed to cooperate with the Company in order to enable the latter to comply with its legal transparency obligations. In connection with the above, the Provider also undertakes to comply with any and all transparency obligations incumbent upon them under the Sunshine Act and to indemnify and hold the Company harmless from any damage, any request or claim that should arise to the Company or companies of the Group from the failure to comply with these obligations by the Provider.

11. Miscellaneous

11.1 This Agreement and its Annexes represent the whole e agreements between the Parties and supersede any prior agreements, oral or written, in relation to the subject matter of this Agreement, which may be in existence between the Parties.

11.2 No changes or modifications to this Agreement are permitted except by an act of all the Parties.

11.3 The Provider may not assign or transfer their rights, duties or obligations under this Agreement nor may they otherwise dispose of them without the prior written consent of the Company.

11.4 The Provider undertakes to fulfil all necessary and sufficient, at their own expense, for the proper execution of the Agreement, as well as to acquire all authorizations, the permits, authorizations required by applicable law and necessary for the proper execution of this Agreement. The Company is therefore released without exception or reservation from any form of liability for damages or otherwise that may arise to itself or to Group Companies as a result of or in connection with the execution of this Agreement.

11.5 The Parties undertake to keep the content of this Agreement confidential, without prejudice to the provisions of art. 10.

11.6 This Agreement is governed by and construed in accordance with the laws of Italy.

11.7 ***[Option 1]*** The Parties shall submit disputes arising under this Agreement to the conciliation service of the Arbitration Chamber of Milan. In the event that the attempt fails, disputes arising out of or relating to this Agreement shall be settled by arbitration according to the Rules of the Milan Arbitration Chamber, by a single arbitrator/ three arbitrators appointed in accordance with these Rules. or ***[Option 2]*** The Parties undertake to settle amicably any dispute that may arise between them; in the event of failure, the sole exclusive competent court shall be the Court of [***] ***[NOTE: insert the place of business of the Company].***

12. Final Provisions

12.1 The tolerance of one of the Parties in the face of the failure of the other Party to comply with any of the provisions of this Agreement shall not constitute or be interpreted as a tolerance to subsequent contractual violations committed by the same Party nor prejudice rights arising.

12.2 The Parties expressly agree that the invalidity of any provision of this Agreement will not affect the validity of this Agreement in its entirety. The Parties hereby undertake, in such a case, to endeavour to replace this clause within the Agreement so as to comply with the mandatory rules of law.

13. Negotiations

13.1 This Agreement has been the subject of negotiations between the Parties, therefore, Articles 1341 and 1342 of the Italian Civil Code are not applicable.

With the signatures below, the Parties agree and undertake to comply with the terms and conditions of this Agreement.

The parties are free to conclude this Agreement by means of correspondence by certified electronic mail and digital subscription.

_____, _____

Company _____
Provider _____

Annex 1: Event Agenda

ANNEX 1

EVENT AGENDA