SPONSORSHIP AGREEMENT FOR NON-CME EVENT (SPONSOR - HCO/PCO)

CONFINDUSTRIA
Dispositivi Medici

This Sponsorship Agreement for a Non-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 the*** HCO/PCO***]***, having its registered office in [***], fiscal code and VAT number [***], registered with the ECM Provider Register under number [***] hereby represented by its legal representative pro tempore [***] (hereinafter the "**HCO**"/the "**PCO**"). 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, production, commercialization and/or sale of medical technologies;
ii. the HCO/PCO is ***[NOTE: please insert description of the*** HCO/PCO ***together with some details]***;
iii. the HCO/PCO intends to organise an educational event for Healthcare Professionals ("HCPs") entitled **[name of the event]**, as per the agenda attached to this Agreement under Annex 1, on **[date]** in **[location and venue]** (hereinafter the "Event") and to avail of a financial contribution for the management and implementation of the Event;
iv. the Company, considering the relative scientific and educational importance of the Event, is willing to contribute to the organisation and realisation of the same in compliance with the Confindustria Medical Devices Code, Medtech Europe and anti-corruption legislations and any other and further regulations applicable to the activities covered by this Agreement;

NOW, THEREFORE

the Parties thereby agree and stipulate as follows:

1. Contribution

1.1 The Company agrees to provide the HCO/PCO with a financial contribution in the amount of [***amount in letters]*** euro [€ ***amount in figures***] as provided for and for the purposes set forth in Article 1.3 below (hereinafter "**Contribution**"). It is understood that the Contribution shall be understood to be net of VAT and that the Company shall not be required to pay any further amounts for any reason in connection with this Agreement.

1.2 The payment of the Contribution shall be made by the Company within [***] days from the signature of this Agreement by both 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

Holder: [***]

Banking Institute: [***]

IBAN Code: [***]

BIC Code: [***]

1.3 HCO/PCO will use the Contribution exclusively for the following purposes

a) to cover registration, travel and accommodation costs for the number of healthcare professionals, chosen independently by HCO/PCO, in relation to the Event

b) to cover costs related to the organisation of the Event (e.g. speaker costs)

c) **(NOTE: insert any further details where applicable)**

It is understood that any use of the Contribution for purposes other than those referred to in this Article 1.3 shall be subject to the prior written approval of the Company and may in any case be exclusively related to another training event other than the one referred to in Annex 1.

1.4 The Parties agree that the Contribution has exclusively scientific and/or educational purposes and is not intended in any way directly or indirectly to promote the Company"s products, services or commercial activities.

2. Ethics and Compliance

2.1 The HCO/PCO warrants that the Contribution shall be used

a) in full compliance with the Code of Ethics of Confindustria Dispositivi Medici (latest version) and all applicable laws and legislation (including data protection laws) and industry codes of conduct. By way of example but not limited to, the HCO/PCO shall not use the Contribution for entertainment activities, extra-luxury hotels, participation in social events, coverage of expenses related to accompanying persons of the selected medical professionals;

b) in full compliance with the principles of transparency;

c) where applicable, only after approval of the Event by the Conference Vetting System of MedTech ("CVS") or the Conference Evaluation System ("SVC") of Confindustria Dispositivi Medici.

2.2 The Parties expressly agree that the granting of the Contribution shall in no way be intended to promote or lead to the conclusion of a contract with the HCO/PCO, concerning the purchase, hire, recommendation, prescription, use, supply or order of the Company"s products or services, nor shall it be made as a reward for past purchases, uses, orders, recommendations or prescriptions.

2.3 Lastly, the HCO/PCO 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 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 of the Event. The HCO/the PCO shall directly pay and/or reimburse the Company for any additional registration and/or authorisation fee or cost and expense relating to the procedure with AIFA under 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 HCO and/or the PCO or of any other party relied upon by them in connection with the said procedure. ***[NOTE: delete where not applicable]***.

3. Use of the Contribution

3.1 The Contribution is intended for scientific and/or educational purposes and shall not be used, not even in part, to promote commercial activities or the products of the Company. The HCO/PCO undertakes to use the amount of the Contribution in connection with what is stated in article 1.3 and not for leisure, recreational or social events nor for accompanying persons (e.g. family members) of the selected health care professionals.

3.2 The HCO/PCO undertakes to give evidence of the Contribution to the realisation of the Event by the Company, by means of the placing of the Company"s logo in the materials related to the Event and by inserting the wording "with the unconditional contribution of XXX".

4. Independent Selection

4.1 The Company shall not be involved in any way in the selection of the individual Healthcare Professionals who shall benefit from the Contribution, nor in the organisation of the Event and, inter alia, in the selection of the speakers and/or moderators and the related contracting, definition of the programme, and more generally in the management and conduct of the Event, and the aforesaid responsibilities shall be the exclusive responsibility of the HCO/the PCO.

5. Verification and Review Rights

5.1 Following the Event, the HCO/the PCO shall provide the Company with a report on the use of the Contribution and/or appropriate documentation evidencing the use of the Contribution in accordance with the terms and conditions of this Agreement. Notwithstanding the foregoing, the HCO/the PCO shall under no circumstances provide the Company with a list of the healthcare professionals who have attended/participate in the Event with the Company"s Contribution. Should the Event be sponsored by more than one Company, the HCO/PCO may provide the aggregate list of the Healthcare Professionals who have benefited from the Contribution, in compliance with privacy regulations.

5.2 Without prejudice to internal legal, tax and accounting obligations and/or applicable laws that the Company may have to comply with and without prejudice to the provisions of art. 5.1 above, the HCO/the PCO agrees that the Company may, on its own behalf or through an independent third party and at any time, upon [***] days" notice, conduct an audit of the HCO/the PCO in order to verify the compliance of the use of the Contribution in accordance with this Agreement and, for such hypothesis, the HCO/ the PCO shall grant full access to all necessary information and shall cooperate as far as reasonably possible.

6. Unused Funds

6.1 If the Contribution or any part thereof remains unused for any reason whatsoever, including if the Event is cancelled for any reason whatsoever, the HCO/PCO shall give immediate written notice thereof to the Company and shall promptly return to the Company and in any event within [***] days from the date of cancellation of the Event or early termination or natural expiry of this Agreement, the unused Contribution or part thereof.

7. Duration and Resolution

7.1 This Agreement will be effective from the date of execution (hereinafter the "**Effective Date**") and will remain in force until the conclusion of the Event, or until the date of cancellation of the Event, without prejudice to the application of the 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 HCO/the PCO, via PEC or registered letter with return receipt, in accordance with article 1454 of the Italian Civil Code, in the event of a serious breach of contract by the HCO/the PCO that is not remedied within fifteen (15) days from the date of receipt of the relevant notice to comply. In this case, the provisions of article 6 shall apply regarding the return of the Contribution or the unused part of the Contribution, with the obligation for the HCO/PCO to provide a detailed account of the part of the Contribution used.

7.3 The Company will also have the right to terminate this Agreement with immediate effect, by means of a written notice to that effect sent to the HCO/the PCO, in accordance with article 1456 of the Italian Civil Code, via PEC or registered letter with return receipt, when expressly provided for in this Agreement.

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 in the event of declaration of non-conformity of the Event with the provisions of the Code of Ethics of MedTech Europe or Confindustria Dispositivi Medici, this Agreement shall be considered as never concluded and without effect, with the obligation for the HCO/the PCO to provide for the immediate return of the Contribution to the Company, no later than 3 working days from the related request.

8. Code of Ethics and Legislative Decree 231/2001

8.1 The HCO/the PCO 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 HCO/the PCO undertakes to indemnify the Company from now on for any penalties or damages that may be incurred by the latter as a result of the violation of the aforementioned Code of Conduct and D. lgs. 231/2001 by the HCO/the PCO or its own personnel.

8.2 The HCO/the PCO also undertakes to report to the Supervisory Board, at the address [***], cases of violations of the Code of Conduct of the Company as well as in the case of the commission of offences provided for by Legislative Decree 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 HCO/ the PCO declares and guarantees that personal data relating to its employees and collaborators, as well as to the participants in the Event (hereinafter "personal data"), will be processed in full compliance with Regulation (EU) 2016/679 ("GDPR") and the applicable national legislation (Legislative Decree 101/2018 and the Measures of the Garante).

10. Transparency Obligations

10.1 The HCO/the PCO 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 HCO/the PCO 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 HCO/the PCO 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 HCO/the PCO.

11. Miscellaneous

11.1 The HCO/PCO undertakes to execute the Event, to carry out its individual stages and to do everything necessary and sufficient, at its own care and expense, for the proper execution of this Agreement, as well as to acquire all authorisations, permits, and clearances prescribed by the regulations in force and necessary for the proper execution of the Event. The Company is therefore relieved without exception or reservation from any form of liability for any damage or other harm that may be caused to persons or property as a result of or in connection with the performance of the Event in all its stages

11.2 The HCO/PCO shall be liable towards third parties and the Company for damages resulting from the non-fulfilment of contractual obligations. During the execution of this Agreement, the HCO/PCO shall be liable for damages arising to third parties from the actions of the employed personnel and shall therefore take all necessary measures and precautions, with the obligation to monitor, in order to ensure safety and preventative conditions.

11.3 The HCO/the PCO undertakes to indemnify and hold harmless the Company against any and all liability for damages to persons or property that may occur in connection with this Agreement, and against legal actions arising from claims for damages brought against the Company by damaged third parties.

11.4 This Agreement and its Annexes represent the entirety of the agreements between the Parties and supersede any and all prior agreements, oral or written, relating to the subject matter of this Agreement that may exist between the Parties.

11.5 No amendments or variations to this Agreement are permitted except by an act signed by all Parties.

11.6 The Parties agree that each Party shall be independent of the other and that this Agreement shall not be deemed to create a partnership, joint venture, representation or other similar relationship.

11.7 The HCO/PCO shall not assign or transfer its rights, duties or obligations under this Agreement nor dispose of them otherwise without the prior written consent of the Company.

11.8 The Parties undertake to keep the contents of this Agreement confidential, without prejudice to the provisions of Article 10.

11.9 This Agreement shall be governed by Italian Law.

11.10 **[Option 1]** The Parties shall submit disputes arising from this Agreement to the conciliation attempt provided by the Conciliation Service of the Chamber of Arbitration of Milan. In the event that the attempt fails, disputes arising out of or in connection with this Agreement shall be settled by arbitration in accordance with the Rules of the Chamber of Arbitration of Milan, by a sole arbitrator/three arbitrators, appointed in accordance with said Rules. or **[Option 2]** The Parties undertake to amicably settle any disputes 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.

By signing this Agreement, the Parties agree to the terms and conditions of this Agreement.
[…], the […]

Company _____
HCO/PCO _____

Annex 1 - Description of the Event
Annex 2 - Contribution Details

ANNEX 1

EVENT AND AGENDA

ANNEX 2

CONTRIBUTION DETAILS

A- Selection Criteria and Event Details

[NOTE: It should be noted that the criteria indicated by the Company must not be specific enough to allow individual Health Professionals to be identified or attributable to them. Individual companies will ensure the application of the above].

EVENT TITLE
PLACE
DATE
HCP NUMBER
RECRUITING CENTRES
HCP SPECIALISATION

B - Economic conditions

REGISTRATION
ACCOMMODATION
MEALS
TRAVEL
OTHER (Specify)

- Other