

MEETING INTERNATIONAL COMPLIANCE

What Your Medical Meeting Needs to Know for 2018 and Beyond



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*Meeting International Compliance-
What Your Medical Meeting Needs to Know
for 2018 and Beyond*

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MEET • LEARN • EXPERIENCE

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#HCEAConnect

What is MedTech Europe

MedTech Europe is the European trade association representing the medical technology industries.

MedTech Europe was created with via joint venture between EDMA, representing the European in vitro diagnostic industry; and Eucomed, representing the European medical devices industry and promotes a balanced policy environment that helps the medical technology industry meet Europe's growing healthcare needs and expectations.

Background

BloombergBusiness

Stryker to pay \$13.2 mln to settle civil bribery charges

The New York Times

**Inquiry Into Foreign Bribes at Biomet Hangs Over
\$13 Billion Merger**

Medtronic Agrees to \$23.5 Million Settlement in Kickback Case

LE SOIR

**Le patron de Mithra Pharmaceutical sous le
coup d'une instruction judiciaireLe Soir**

The Industry self regulating actions

To regulate interactions between MedTech Europe members and healthcare professionals

- **Code of Ethical Business Practice (2008), revised in 2015**

To have a practical implementation of the Code

To address MedTech Europe members' divergent interpretation of the Code

To reduce risk associated to industry sponsorship of HCPs to third-party educational events

- **The Conference Vetting System (2012)**

Respecting Ethical Standards- FIVE PRINCIPLES

- ❑ Reduce compliance/bribery risks – unilateral transfer of value
- ❑ Uphold value and promote responsible industry image – Key priority
- ❑ Harmonization of requirements worldwide
- ❑ Potential prevention of new laws – stringent self-regulation
- ❑ Transparency will not end DS challenges by media and judicial authorities

- 1 IMAGE & PERCEPTION-** No luxury hotels, luxurious dinner, resorts, etc.
- 2 TRANSPARENCY-** Informing institutions / superior of any interaction.
- 3 EQUIVALENCE-** Setting fees for services following strict FMV Methodology.
- 4 SEPARATION-** Decision-making is not primarily sales-driven.
- 5 DOCUMENTATION-** Signing the contract and documenting expenses.

The MedTech Code of Ethical Business Practice

Six big changes

- **Phasing out of direct sponsorship**
- **Transparency of educational grants**
- **Common chapter on general criteria for events**
- New chapter on demonstration products and samples
- Agreed definitions
- Common independent enforcement mechanism

2016

2017

2018

2019

“Direct sponsorship”

Companies select individual HCPs and financially support their participation to Third Party Organised Events.



Such financial support typically covers some or all of the travel, lodging and registration costs of the HCP.

“Educational grants”

Companies provide educational grants to **hospitals, medical societies** and other third parties **to support genuine medical education.**



These include educational grants provided to support HCP participation to Third Party Organised Event. **HCPs are selected by the receiver of the grant.**



Renewed
commitment to
**medical
education**

The new Code is a clear message from the medical technology industry that we want to safeguard and protect our relationship with healthcare professionals by adopting a clear and strict self-regulation.

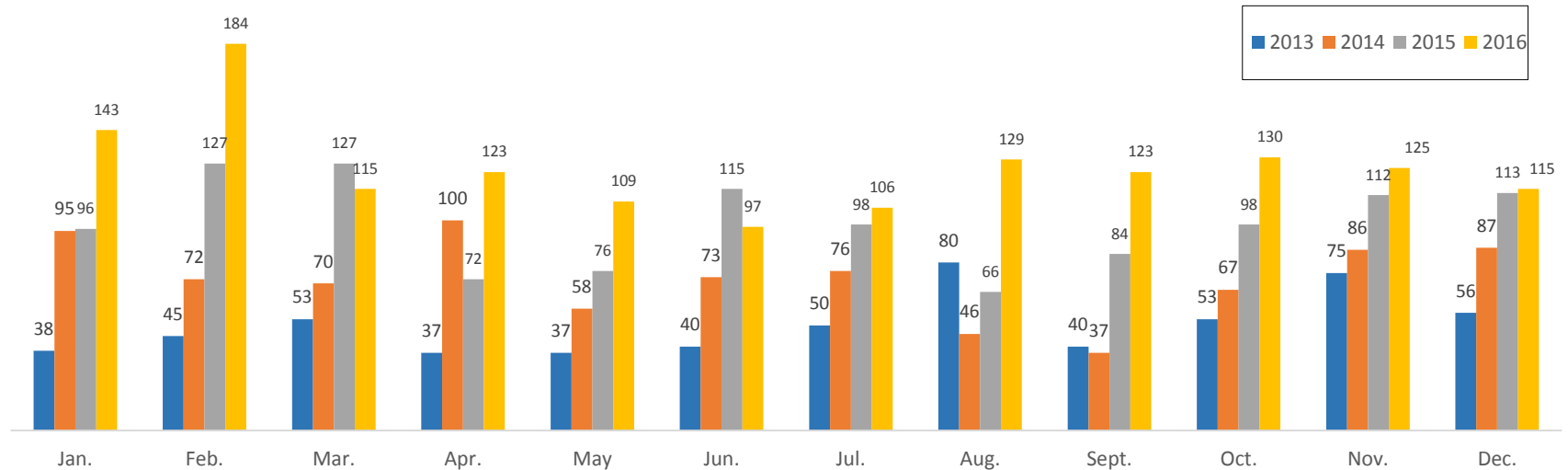
Conference Vetting System (CVS)

- **A centralised decision-making system:** CVS is a unique system in the Medical Device industry used by all MedTech Europe members, Professional Conference Organisers and Scientific Societies.
- CVS **reviews the compliance of third-party educational events with MedTech Europe Code of Ethical Business Practice** and [Mecomed Code of Business Practice](#) (the “Codes”) to determine the appropriateness for companies which are members of MedTech Europe and Mecomed to provide financial support to such events in the form of educational grants or commercial activities (booths, advertising, satellite symposium) CVS renders a binding decision for MedTech Europe and members of the national associations affiliated with MedTech Europe as to whether or not they can financially support healthcare professionals to attend such events.
- The system **operates independently** to ensure objectivity in events assessments.
- **Separate** website & visual **identity:** www.ethicalmedtech.eu

Conference Vetting System (CVS)



Conference Vetting System (CVS)



	2013	2014	2015	2016
Total submissions	604	867	1184	1499
Increase		43%	36%	21%

What type of support for which type of event?

- Educational grants

To support general running of the event

Includes funds to support HCPs

Includes funds to support Faculties

- Commercial Activities

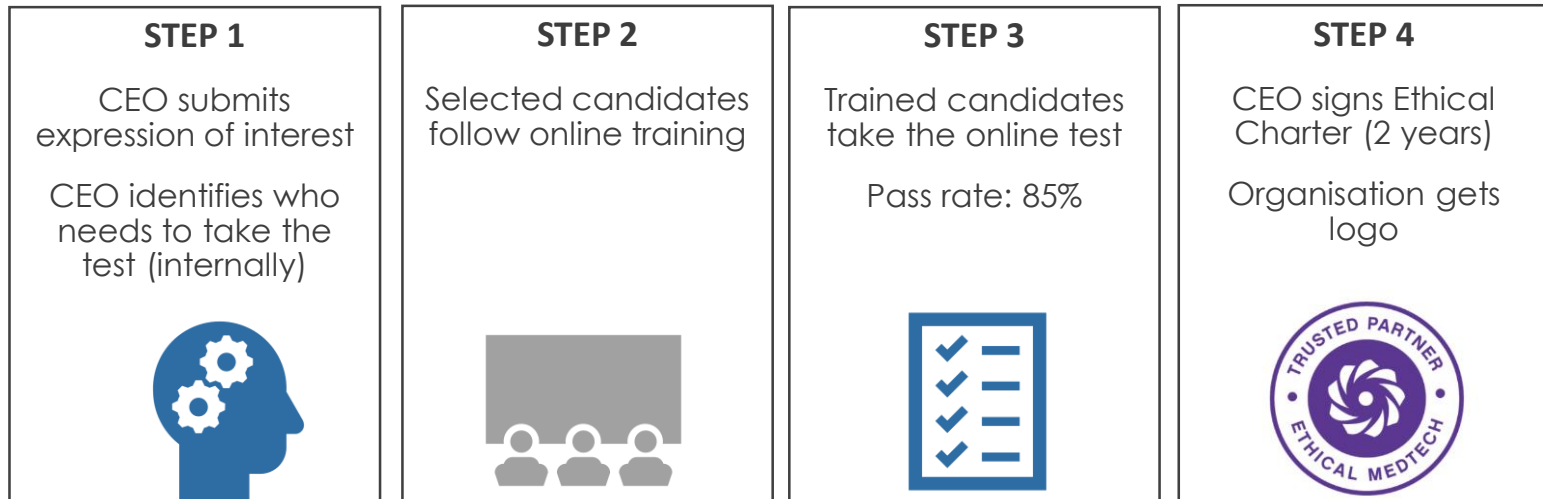
Speakers consultancy
satellite symposia

Booths/advertising

		PRIOR CVS SUBMISSION			
		IN MEDTECH EUROPE GEOGRAPHIC AREA		OUTSIDE MEDTECH EUROPE GEOGRAPHIC AREA	
WHICH TYPE OF SUPPORT CAN MEMBER COMPANIES PROVIDE TO WHICH THIRD PARTY ORGANISED EDUCATIONAL EVENTS?		NATIONAL Third Party Organised Educational Events attended by delegates which are local HCPs only)	INTERNATIONAL (Third Party Organised Educational Events attended by delegates coming from at least two countries of the MedTech Europe Geographic Area ^{1,2})	INTERNATIONAL (Third Party Organised Educational Events attended by delegates who are Healthcare Professionals registered and practising in the MedTech Europe Geographic Area ³)	INTERNATIONAL (Third Party Organised Educational Events to which no Healthcare Professionals registered and practising in the MedTech Europe Geographic Area attend, neither as speakers or delegates)
EDUCATIONAL GRANTS ⁴ PROVIDED TO SUPPORT A THIRD PARTY	Educational Grant to support the general running of a conference	2017 – Allowed ⁵ . 2018 – Allowed.	2017 – Allowed. Not subject to CVS decision 2018 – Subject to CVS decision	2017 – Allowed. Not subject to CVS decision 2018 – Allowed. Not subject to CVS decision	Out of scope of the application of the Code ⁶
	Educational Grants that includes funds to support	2017 – Allowed.	2017 – Allowed. Not subject to CVS decision	2017 – Allowed. Not subject to CVS decision	N/A

The Ethical Charter

- Voluntary certification system displaying HCOs/PCOs' engagement to comply with MTE's Code when organising conferences
- Online Process





Changing the Playing Field

MedTech industry is still fully committed to support independent medical education. However it will be done at arms' length through independent third-parties.
The independent third-party will decide which HCPs receive the funding.

The Current Process

**MED DEVICE
COMPANY**




Med Device
company chooses
attendees and
contacts travel
agency



Agency contacts
Healthcare
Organization and
their International
Group Housing
Department to
arrange for
international group
housing and
registration



International delegations attending US medical meetings are usually sponsored by either a Pharmaceutical or a Medical Device Company. This means that groups of international attendees are invited and all their travel and meeting expenses are paid by the sponsoring company.



Changing the Playing Field

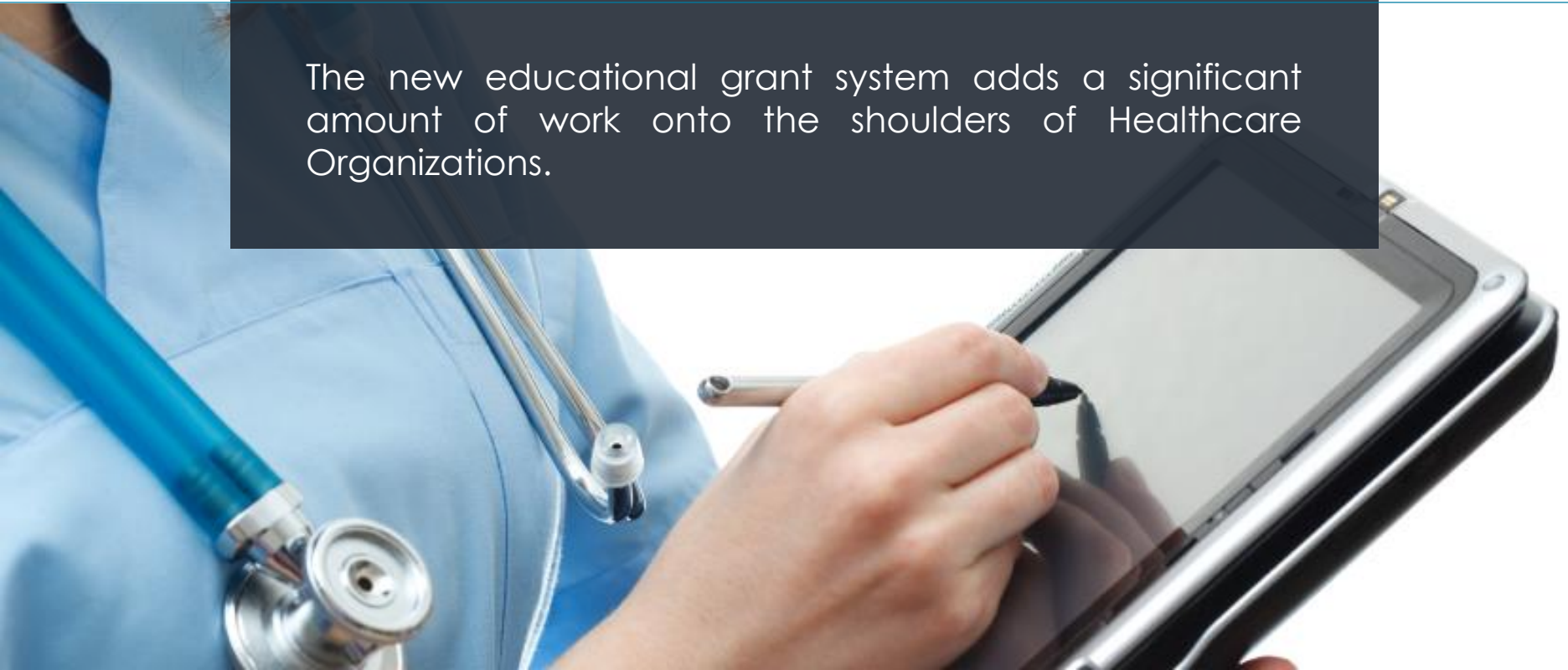
As of 2018, MedTech Europe will require all meetings to be vetted through its Conference Vetting System.

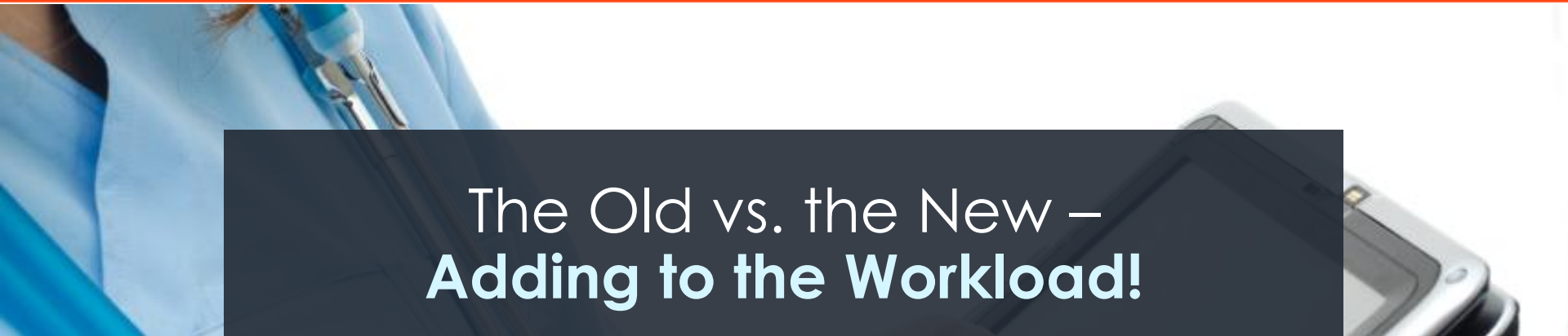
Only vetted meetings will be eligible to receive funds from MedTech Europe member companies, — and only through educational grants.

The most important change for the US Medical Meeting Industry is that MedTech Europe member companies will not be able to directly sponsor an HCP, neither as a delegate nor as a speaker.

The Old vs. the New – **Adding to the Workload!**

The new educational grant system adds a significant amount of work onto the shoulders of Healthcare Organizations.





The Old vs. the New – Adding to the Workload!

1. Conferences supported by medical device companies will need to apply and be in compliance with the Conference Vetting System.
2. Healthcare Organizations will need to write and submit grant requests to each medical device company that sponsors delegations to their medical meeting.
3. Once awarded the grant, Healthcare Organizations will be responsible for choosing the HCPs that will receive support, following the guidelines as set forth on the grant requested.
4. Healthcare Organizations will be responsible for the management of the sponsored HCPs, including figuring out how to contact them, gather their information, manage their travel requirements, etc.
5. Medical Device Companies will need to submit reconciliation and disclosure reports to MedTech Europe transparency platform.



Accreditation Council™
for Continuing Medical Education

**EVEN MORE
COMPLEXITY**

ACCME STANDARDS FOR COMMERCIAL SUPPORT

The CME provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity.



vs.



Healthcare Organizations MUST APPLY for grants from Medical Technology Companies to fund travel, hospitality, and registration for international attendees to attend the medical meeting.



Healthcare Organizations ARE NOT ALLOWED to use funds received from Medical Technology Companies to fund travel and hospitality of attendees without jeopardizing their ACCME Accreditation.

SOLUTION

A third-party non-profit may apply for grants from the Medical Technology Company and use funds to fund travel, hospitality, and registration for international attendees to attend the Healthcare Organization's medical meeting without jeopardizing the Healthcare Organizations ACCME Accreditation.

A seamless process that will allow effortless grant requests for the healthcare organization, as well as targeted selection of health-care professional recipients within the market of the international sponsor.

The NEW Process

**MED DEVICE
COMPANY**



3rd Party
Healthcare
Organization
requests and is
awarded grant
from Medical
Device Company



3rd Party Healthcare
Organization assigns a
grant manager to
provide services



**HEALTHCARE
ORGANIZATION
Medical Meeting**



MED DEVICE
COMPANY



3rd Party Healthcare
Organization
requests and is awarded
grant
from Medical Device
Company



3rd Party Healthcare
Organization assigns a
grant manager to provide
services



HEALTHCARE
ORGANIZATION
Medical Meeting



1

Create and submit the application to The Conference Vetting System

MED DEVICE
COMPANY



3rd Party Healthcare
Organization
requests and is awarded
grant
from Medical Device
Company



3rd Party Healthcare
Organization assigns a
grant manager to provide
services



HEALTHCARE
ORGANIZATION
Medical Meeting



The 3rd-party Healthcare Organization prepares the educational grant.

Grants are submitted to each Medical Technology Company individually, following their preferred grant request format.

Grants will detail how they meet requirements not only to the EthicalMedTech guidelines, but also to any local law and regulations in effect based on location of Medical Technology Company and/or origination of proposed HCP beneficiaries.

2

MED DEVICE
COMPANY



3rd Party Healthcare
Organization
requests and is awarded
grant
from Medical Device
Company



3rd Party Healthcare
Organization assigns a
grant manager to provide
services



HEALTHCARE
ORGANIZATION
Medical Meeting



The 3rd-party Healthcare Organization requests and is awarded grant from Medical Device Company.

Funds from the Medical Device Companies are transferred to the 3rd-Party Healthcare Organization to execute the contracts.

3

The Healthcare Organization assigns a grant manager to provide services.

MED DEVICE
COMPANY



3rd Party Healthcare
Organization
requests and is awarded
grant
from Medical Device
Company



3rd Party Healthcare
Organization assigns a
grant manager to provide
services



HEALTHCARE
ORGANIZATION
Medical Meeting



Grant Manager & 3rd Party Healthcare Organization chooses international healthcare professionals that will attend the annual meeting, meeting the grant guidelines- will provide an online Grant Application process adhering to all grant guidelines, via an approved event website.

4

HCPs may apply to participate as a grant beneficiary and, if they meet the criteria as specified in the grant, are chosen and invited on a first-come, first-served basis.

MED DEVICE
COMPANY



3rd Party Healthcare
Organization
requests and is awarded
grant
from Medical Device
Company



3rd Party Healthcare
Organization assigns a
grant manager to provide
services



HEALTHCARE
ORGANIZATION
Medical Meeting



Grant Manager oversees the secretariat process and airline arrangements through partner travel agencies.

5

Grant Manager engages and pays Healthcare Organization/Medical Meeting for registration, housing, and travel arrangements through current international housing process.

MED DEVICE
COMPANY



3rd Party Healthcare
Organization
requests and is awarded
grant
from Medical Device
Company



3rd Party Healthcare
Organization assigns a
grant manager to provide
services



HEALTHCARE
ORGANIZATION
Medical Meeting



Grant Manager prepares and provides grant reconciliation reports to all Healthcare Organizations and a grant disclosure reports for each Medical Device Company, following requirements based on EthicalMedTech guidelines.

6

Grant Manager will also provide any reports needed based on required laws as per the location of Medical Device Sponsor grant office of origin of HCP beneficiary.

Q

&

A

MedTech Corporate Members

1WorldSync	Cardinal Health	Health Technology Assessment	Novartis NPT	Siemens Healthcare Diagnostics
3M	Cepheid	Hemocue	Novo Nordisk	Smith & Nephew
Abbott	Cerus	Hill-Rom	Olympus	Smiths Medical
Acelity	Cochlear	Hollister	Orange Healthcare	Sophia Genetics
Alcon	Code of Ethics	Hologic	Orion Diagnostica	St. Jude Medical
Alere	Coloplast	Hospira	Ortho Clinical Diagnostics	Stago
Ansell	Convatec	Integra	Orthofix	Stryker
Artsana	Cook Group	Intuitive surgical	Paul Hartmann	Sysmex Europe GmbH
Ascensia	CR Bard	IVD	PerkinElmer	Tecan Group Ltd.
Astute Medical	CVRx	Johnson & Johnson	Philips	Terumo
B Braun	Dako	Livanova	Procter & Gamble	Therakos
Baxter	Dexcom	Luminex	QIAGEN	ThermoFisher Scientific
BD	DiaSorin	Medacta	Radiometer	Tosoh Bioscience
Beckman Coulter	Edwards Lifesciences	MED-EL	Renishaw	USDM
Bellco	Endologix	Medela	Resource Library	W.L. Gore & Associates
Binding Site	Flextronics	Medline	Roche	Werfen
Biocartis	Fresenius	Medtronic	RTI Biologics	Wright Medical Technology
bioMérieux	Fujirebio	Merck	Sanofi	Zimmer-Biomet
Bio-Rad	GE Healthcare	Merit Medical	SCA	
Biosystems	GHX	Microport	Sebia	
Biotronik	Grifols	Molnlycke Healthcare	Second Sight	
Boston Scientific	Haemonetics	Nevro	Sekisui	
BTG	Halyard			



Thank You

Davide Veglia, ABTS Convention Services & Christine Sainvil, Ethical MedTech