Promosso da





Fondazione per l'Innovazione e la Sicurezza in Sanità





Con il patrocinio e contributo di





**INVITATION PROGRAM** 

## ABSTRACT

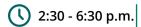
The Medical Device Made of Substance sector is deeply innovating the European therapeutic field.

More and more health needs are covered by innovative therapeutic products that act through a non-pharmacological mechanism of action, and in particular those that use the properties of complex natural substances, which are completely biodegradable in line with the Green Deal principles.

Two are the crucial key factors to express all the innovation in this sector:

- 1. To ensure that the regulation is properly implemented, maintaining the innovative regulatory framework meant by the co-legislator to guarantee safety and therapeutic innovation. In this sense, the correct interpretation of the so-called Rule 21 with reference to the first indent and the definition of a non-pharmacological mechanism of action are two priority aspects.
- Support research, particularly in the field of complex natural substances, by promoting, in accordance
  with the Green Deal principles, a European research platform to evolve the knowledge of the use of
  these substances in the therapeutic field. All the above within a context of Evidence Based Medicine
  open to the homic sciences, to the Real-World Evidence and the biodegradability topics.

## **NOVEMBER 30<sup>TH</sup> | PETRARCA ROOM**



## MEDICAL DEVICES MADE OF SUBSTANCES RESEARCH AND INNOVATION OPPORTUNITIES FOR A SUSTAINABLE HEALTH

Partnership



Moderators Fernanda Gellona Director-General of Confindustria Dispositivi Medici

**Emiliano Giovagnoni** Member of Confindustria Dispositivi Medici

Opening

Eugenio Giani President of Regione Toscana
Simona Bonafè Member of the European Parliament

**Sandra Gallina** • Director General SANTE

Implementation of the Regulation for the Medical Device Made of Substances

The Regulatory Bodies' point of view

**Achille Iachino**DG of Medical Devices and Pharmaceutical Service Italian Ministry of Health

Flora Giorgio • Deputy Head of Unit, B6 Medical Devices and HTA

Maria Grazia Leone Ministero della Salute
Guido Rasi Former Director of EMA

**Fernanda Gellona** Director-General of Confindustria Dispositivi Medici

The Notified Bodies' point of view

Francoise Schlemmer Associazione Team-NB, The European Association Medical Devices of Notified Bodies

Silvio Brusaferro President of Istituto Superiore di Sanità

**Roberta Marcoaldi** Director General of Istituto Superiore di Sanità as Notified Body

The Industry's point of view

Mario FederighiMember of Confindustria Dispositivi MediciEmiliano GiovagnoniMember of Confindustria Dispositivi Medici

An European Research Platform For The Use Of Natural Substances In Therapy

**Patrizia Toia** • Vice-President Commission Industry, Research and Energy of the European Parliament

Marco Racchi SIF Italian Society of Pharmacology - Pavia University

The first scientific journal entirely dedicated to Medical Devices Made of Substances

**Alessandro Mugelli** Specialty Chief Editor Substance-Based Medical Devices

Round Table Closing remarks

Simona Bonafè Member of the European Parliament

**Patrizia Toia** • Vice-President Commission Industry, Research and Energy of the European Parliament

**Antonio Tajani** • Chair of the Conference of Committee Chairs and Committee Affairs

Undersecretary of State for European Affairs **Vincenzo Amendola** has been invited

**EVENT REGISTRATION** 

**ZOOM WEBINAR SESSION** 

https://us02web.zoom.us/webinar/register/WN\_swLG1jflQAGZTVqbfBnTjw

6:30 p.m. • Closing afternoon works



**#FORUMRISK16** 



