

Promosso da



Fondazione
per l'Innovazione
e la Sicurezza
in Sanità



Con il patrocinio e contributo di



Forum Risk Management

obiettivo sanità & salute

NOVEMBER 30TH • 2:30 - 6:30 PM
PETRARCA ROOM

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



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.
2. 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 homio sciences, to the Real-World Evidence and the biodegradability topics.



2:30 - 6:30 p.m.

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

Partnership



Moderators

Fernanda Gellona
Emiliano Giovannoni

Director-General of Confindustria Dispositivi Medici
Member of Confindustria Dispositivi Medici

Opening

Eugenio Giani
Simona Bonafè
Sandra Gallina ●

President of Regione Toscana
Member of the European Parliament
Director General SANTE

Implementation of the Regulation for the Medical Device Made of Substances

The Regulatory Bodies' point of view

Achille Iachino
Flora Giorgio ●
Maria Grazia Leone
Guido Rasi
Fernanda Gellona

DG of Medical Devices and Pharmaceutical Service Italian Ministry of Health
Deputy Head of Unit, B6 Medical Devices and HTA
Ministero della Salute
Former Director of EMA
Director-General of Confindustria Dispositivi Medici

The Notified Bodies' point of view

Francoise Schlemmer
Silvio Brusafferro
Roberta Marcoaldi

Associazione Team-NB, The European Association Medical Devices of Notified Bodies
President of Istituto Superiore di Sanità
Director General of Istituto Superiore di Sanità as Notified Body

The Industry's point of view

Mario Federighi
Emiliano Giovannoni

Member of Confindustria Dispositivi Medici
Member of Confindustria Dispositivi Medici

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

Patrizia Toia ●
Marco Racchi

Vice-President Commission Industry, Research and Energy of the European Parliament
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
Patrizia Toia ●
Antonio Tajani ●

Member of the European Parliament
Vice-President Commission Industry, Research and Energy of the European Parliament
Chair of the Conference of Committee Chairs and Committee Affairs

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

EVENT REGISTRATION

https://us02web.zoom.us/webinar/register/WN_swLG1jflQAGZTVqbfBnTjw

ZOOM WEBINAR SESSION

6:30 p.m. • Closing afternoon works



#FORUMRISK16



@FORUMRISK