



# Safer medical devices: Implementation of the EU MDR and EUDAMED database

# ABOUT US

We are a network of thousands of hospitals, healthcare leaders, and healthcare professionals, with members across Europe and partners across the globe.

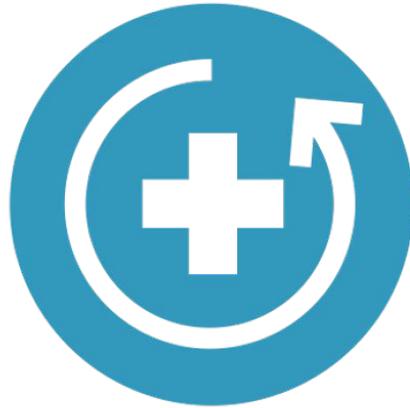
Together we prove that it's possible to deliver the highest quality of care in a way that's sustainable environmentally and financially.



# OUR PROGRAMMES



CLIMATE-SMART  
HEALTHCARE



CIRCULAR  
HEALTHCARE



SAFER  
PHARMA



SUSTAINABLE  
FOOD

# GLOBAL GREEN AND HEALTHY HOSPITALS

THE HEALTHCARE  
PROVIDERS AT THE HEART  
OF OUR ORGANISATION



132 members in 21 countries  
across the WHO Europe region

# CIRCULAR HEALTHCARE

## STRATEGIC GOAL

European health systems drive markets towards toxic-free products that conserve finite resources, minimise waste, and contribute to an ethical supply chain and circular economy.



# RESOURCES

## European healthcare's phase-out list for chemicals of concern

## A step forward in phasing-out harmful chemicals: The role of healthcare: Call for action!!

Past resources on MDR and Toxic healthcare can be found here: [CH website](#)



**Health Care Without Harm Europe**

### European healthcare's phase-out list for chemicals of concern

29 November 2021

The European healthcare sector seeks to phase out chemicals of concern from supply chains and medical products and accelerate the phase-out of the highest priority chemicals of concern.

The healthcare sector will continue working with suppliers to achieve this goal. Exemptions to the criteria will be made when safer alternatives do not exist and when specially requested in tenders for essential use.

**Chemicals of concern criteria:**  
Note limit values where indicated.

- Candidate list of substances of very high concern (SVHCS)** – All articles or component articles of a complex article do not contain substances listed on the [Candidate List](#)<sup>1</sup> of the EU chemicals regulation REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals EC 1907/2006) over 0.1% weight by weight (w/w).
- Carcinogenic, mutagenic or substances toxic to reproduction (CMR substances of category 1A or 1B)** – All articles in accordance with Article 52 and 10.4.1 of Annex I of the [Medical Device Regulation](#) (MDR)<sup>2</sup> do not contain substances which are CMR of category 1A or 1B in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 (CLP) over 0.1% (w/w).
- Polyvinyl chloride (PVC)** – All articles or component articles of a complex article do not contain PVC.
- Phthalates** – All articles or component articles of a complex article do not contain Phthalates listed on the Candidate List or [Restriction List](#)<sup>3</sup> of the REACH Regulation, nor on the [ChemSec SIN List](#)<sup>4</sup> over 0.1% (w/w).

<sup>1</sup> Candidate List: [echa.europa.eu/da/candidate-list-table](https://echa.europa.eu/da/candidate-list-table)  
<sup>2</sup> The MDR [eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745)  
Endocrine-disrupting substances in the MDR are covered by the Candidate List and the restricted Phthalates.  
<sup>3</sup> Restriction List: [echa.europa.eu/da/substances-restricted-under-reach](https://echa.europa.eu/da/substances-restricted-under-reach)  
<sup>4</sup> ChemSec SIN List: [sinlist.chemsec.org](https://sinlist.chemsec.org)

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- Bisphenols** – All articles or component articles of a complex article do not contain leachable Bisphenols (not bound to the material) exceeding a 0.1 mg/l (migration limit).
- Flame retardants** – All articles or component articles of a complex article do not contain flame retardants, unless specifically requested.  
  
When flame retardancy is requested, substances on the Candidate List, the Restriction List, or the SIN List over 0.1% (w/w) should not be used.
- Antimicrobial agents** – All articles or component articles of a complex article do not contain intentionally added antimicrobial agents to reduce surface pathogens, unless specifically requested.
- Per- and polyfluoroalkyl substances (PFAS)** – All articles or component articles of a complex article do not contain stain- or water-repellent treatments that contain total PFAS over 0.1% (w/w).

<sup>1</sup> PFAS, as defined by the OECD: [oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/CBC/MONO\(2021\)25&docLanguage=en](https://oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/CBC/MONO(2021)25&docLanguage=en)

# SPEAKERS



**Oliver Bisazza**

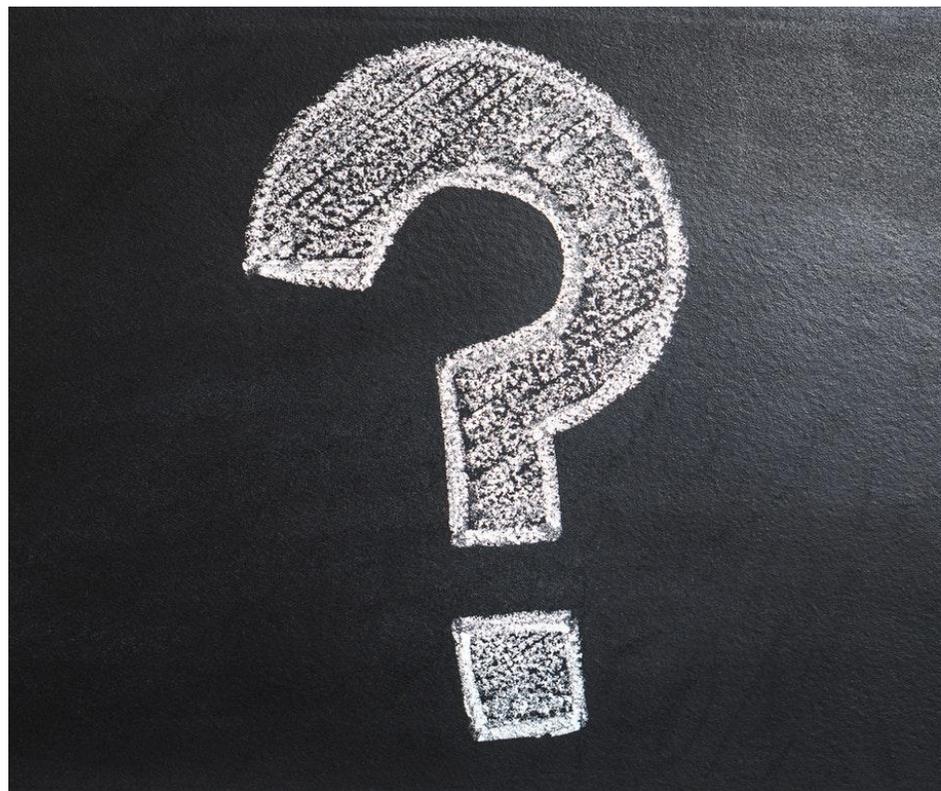
Director, Regulations &  
Industrial Policy  
*MedTech Europe*



**Françoise Schlemmer**

Director  
*Team Notified Bodies*

# Q&A





**NO HARM**

**THANK YOU!**

Please send any further questions to: [kpacella@hcwh.org](mailto:kpacella@hcwh.org)

**NOHARM.ORG**

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