Curriculum Vitae

Personal information

Steffen Luckner

Work experience

Since May 2022 Policy Officer, Federal Ministry of Health, Division 124 (Medical Device Safety)

- Responsibility for Medical Device Software, Cybersecurity and Artificial Intelligence as well as IVD
- Participation in the relevant legislative procedures
- Responsibility for the Designation of the German EU reference laboratory in the field of IVD

June 2021 - April 2022 Policy Officer, Federal Ministry of Health, Division 123 (Medical Device Law) and Division 124 (Medical Device Safety)

- Responsibility for the availability of SARS-CoV-2 antigen tests
- Drafting and supervision the funding program for SARS-CoV-2 PoC NAT tests
- Participation in the legislative procedure of the EU Artificial Intelligence Act

November 2020 - June 2021 Policy Officer, Federal Ministry of Health, Division 123 (Medical Device Law)

- Responsibility for the availability of SARS-CoV-2 antigen tests
- Drafting and supervision the funding programs for SARS-CoV-2 antigen tests and for SARS-CoV-2 PoC NAT tests

October 2020 - November 2020 Policy Officer, Federal Ministry of Health, Division 124 (Medical Device Safety)

April 2019 - October 2020, Policy Officer, Federal Ministry of Health, Division 512 (Cybersecurity and Interoperability)

- Responsibility for interoperability and cybersecurity in healthcare
- Participation in the legislative procedure of the Digital Healthcare Act and participation in the drafting of the Digital Healthcare Modernization Act

July 2017 - April 2019 Policy Officer, Federal Ministry of Health, Division 118 (Medical Device Law)

- Responsibility for Medical Apps, Cybersecurity, Market Surveillance
- Participation in the drafting of the Implant Register Act

Education and training

July 2017 M.Sc. Biomedical Engineering at the Technische Universität Berlin (Germany)

May 2014 B.Sc. Mechanical Engineering at the Technische Universität Berlin (Germany)

Additional information

Publications

Luckner S, Lauer W. Regulatorische Einordnung KI-basierter Produkte für die medizinische Anwendung auf Basis von EU AI Act und MDR/IVDR [Regulatory classification of AI-enabled products for medical use on the basis of the EU AI Act and MDR/IVDR]. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2025 Aug;68(8):854-861. German. doi: 10.1007/s00103-025-04091-9. Epub 2025 Jul 4. PMID: 40643665; PMCID: PMC12287106.

Projects

Memberships

Member of

- MDCG WG 7 on New Technologies
- MDCG WG 10 on International Matters
- MDCG WG 11 on In-vitro Diagnostic Medical Devices
- MDCG WG 13 on Annex XVI Products

Alternate member of

- MDCG WG 2 on Standards
- MDCG WG 3 on Clinical Investigation and Evaluation
- MDCG WG 9 on Unique Device Identification

Other Relevant Information