

Meeting Agenda “Notified Body tips & tricks and MDR Regulatory Insights”

Meeting Date: 21 May, 2025

Time: 10:30 – 14.30 (lunch provided)

Location: UL Solutions, Admiral-Rosendahl-Str. 9, 63263 Neu-Isenburg

Speaker: *Annette Van Raamsdonk, Manager Quality and Regulatory Affairs Program, EMERGO by UL*

Language: English

Registration: www.gha.health/veranstaltung/24-sitzung-des-stammtisches-regulatory-als-workshop-in-praesenz/

10.30 – 11.00 Walk in & Coffee

11.00 – 11.15 Introduction

*Armin Smajilovic, Chairman „Regulatory“ group Kimetec GmbH, Director Business Development
Armin Platz, EMERGO by UL, Senior Sales Executive Medical Market Access*

11.15 - 12.00 EU Regulatory update and current state of play

What to expect?

When approaching a Notified Body it is crucial to be informed about the latest regulatory updates. During this part of the meeting, Emergo will share insights they receive as stakeholders at the European Commission Medical Device Coordination Working Group (MDCG).

- Transitional timelines
- Upcoming guidances
- EUDAMED
- Regulatory changes that may impact your market strategy

12.00 – 12.30 Which factors need to be considered when picking a Notified Body

- Previous certifications
- Classification
- Where to market
- Size and location of the company

12.30 – 13.00 Lunch

Offered by Emergo by UL

13.00 – 14.30 Tips, tricks and best practices

- Low hanging fruits – do’s and don’ts
- Routes to Conformity Assessment and procedures
- Structured dialogue and certificates under condition
- Meeting with your Notified Body
- Questions of the participants

14.30 Closing