

# STRUCTURED DIALOGUE

## The Key to an Efficient Certification Process



### WHAT IS STRUCTURED DIALOGUE?

Information exchange between manufacturer and Notified Body to clarify, in advance, procedural details, timelines, and regulatory aspects relevant to the MDR certification process.

## 01

### STRUCTURED-BASED APPROACH

Meetings planned prior to the formal request for conformity assessment, to optimize certification procedures.



## 02

### INCREASED EFFICIENCY AND PREDICTABILITY

Optimize all planned steps of the certification process, maximizing fluidity and avoiding incomplete submissions.

## 03

### INDEPENDENCE AND IMPARTIALITY

Ensure transparency while maintaining the Notified Body's independence and impartiality.



## GOAL



**PREVENT POTENTIAL OBSTACLES BY FACILITATING A BETTER UNDERSTANDING OF ALL PROCEDURAL ASPECTS THAT AFFECT THE EFFICIENCY OF THE CERTIFICATION PROCESS.**

## BENEFITS FOR MANUFACTURERS

More confidence in addressing complex issues

Enhanced ability to assess the validity of their own regulatory strategy

Clearer definition of key procedural and regulatory aspects

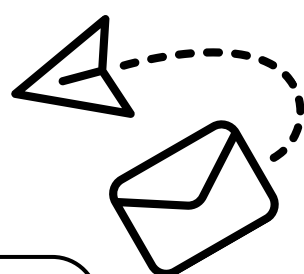


## CONTACT US

to start a structured dialogue!

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