



Ente
Certificazione
Macchine
Notified Body 1282

ENGAGE IN A STRUCTURED DIALOGUE WITH ECM

MDR 2017/745

rev Feb.2025



Optimize the MDR
certification process
through an effective and
transparent structured
dialogue, respecting the
independence of the
Notified Body.



WHAT IS STRUCTURED DIALOGUE?

The formal process enabling manufacturers to clarify, **before submission**, procedural details, timelines, and regulatory aspects relevant to the certification process.

HOW DOES IT WORK?



Information exchange based on meetings planned **prior to** the formal request for conformity assessment.



WHAT BENEFITS?

- ✓ Enhance regulatory awareness
- ✓ Optimize all planned steps of the certification process
- ✓ Avoid incomplete submissions
- ✓ Align regulatory expectations early in the process



CONTACT US

START A STRUCTURED DIALOGUE WITH ECM!

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