

LEVELS OF LANGUAGE REQUIREMENTS FOR MEDICAL PRODUCTS IN EU



UNION-LEVEL LANGUAGE REQUIREMENTS

Generic language requirements and recommendations as defined by MDR/IVDR/CTR, GPSR, EC, or MDCG/CTCG industry guidance.



NATIONAL-LEVEL LANGUAGE REQUIREMENTS

Local/national language requirements and recommendations as determined by NCAs/Member States or NBs/ECs.



PRODUCT-LEVEL LANGUAGE REQUIREMENTS

Specific language requirements determined by the characteristics of the device or drug and its use.