

CLINICAL TRIALS WITH MEDICAL DEVICES (CE BRAND)

- **CONTRACT** and **BUDGET TEMPLATES** completed in Spanish (may also be signed in English, but the Spanish signature is required)
- Protocol
- Favourable opinion of the **Ethic Committee (ECRmp)**
- Qualification of the study by **AEMPS** (Spanish Medications and Healthcare Products Agency)
- **INSURANCE.** - It is not required (unless **Ethic Committee** considers that it is necessary).
- **APPROVAL BY THE CENTRE MANAGEMENT.** - Issued by our **Ethic Committee (ECRmp)**. This document will include the **HULP CODE**. You must contact with:

sol.gracia@salud.madrid.org

maribel.arribas@salud.madrid.org

- **NOTARIZED DOCUMENTATION OR WITH HAGUE APOSTILLE of:**

WHO SIGNS THE AGREEMENT?	REQUIRED DOCUMENTATION
Sponsor signs in his own name and representation	Powers of Sponsor's legal representative
CRO signs on behalf of Sponsor	Powers of legal representative of the CRO
	Sponsor's letter of delegation to the CRO

CLINICAL TRIALS WITH MEDICAL DEVICES (WITHOUT CE BRAND) ´

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- Protocol
- Favourable opinion of the **Ethic Committee (ECRmp)**
- Authorization of the study by **AEMPS** (Spanish Medications and Healthcare Products Agency)
- **INSURANCE.** - Must always include HULP, FIBHULP and the PI
- **APPROVAL BY THE CENTRE MANAGEMENT.** - Issued by our **Ethic Committee (ECRmp)**. This document will include the **HULP CODE**. You must contact:

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