HANDBOOK: CE Mark PPE

By

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1. Difference between PPE & Medical Device:

First, we need to distinguish between PPE and Medical Device.

If you want to protect others, its covered under MEDICAL Category
&
If it's for own protection it is PPE Category

So it's important that you determine which category is your product

MEDICAL DEVICES	PPEs
Instruments , devices, clothing etc. that are used to protect patients or used for patients . It may include surgical instruments, Gowns for protection of patients from contamination or any other item used for patients protection	**Items used for own protection** KN-95 Mask (FFP1,2,3), Surgical Masks, Face Shields, Googles , Gloves, Gowns for own protection (Examination, Impervious Cover Gown, Isolation Gown), Coverall, Apron Note: Surgical mask if worn by patient to protect others can also be taken in Medical Category

2. Categories of PPEs:

There are 3 categories of PPEs:

Category I: Low Risk (where there is no harm to human life or property)

Procedure	1. Select EU Directive (i.e. 2016/425/EEC) and applicable international Std (i.e. EN 149, EN 166 etc. as per the product requirement) 2. Prepare Technical File 3. Perform own test / inspection or get some tests done locally 4. Select any European Union Authorized Representative (**EUAR**)* Other Features: ▪ This will be Self Declaration and you can used CE Mark. ▪ Technical File will be available with EUAR who will review status every year and will charge annual fee ▪ EUAR will issue a certificate only as a token of assurance & compliance *Note: In case of Class I (Medical device) Registration with respective Ministry of Health is required but not for PPE*
NB & EU Rep	Only you require EU Rep *(Any company registered in any EU country and is a legal entity as per EU law)
Testing	Optional You can perform internally or through local Lab preferably accredited
QA/ Site Inspection	Not required

Category 2: Medium Risk (where an individual can have harmful effect or injury but no risk of death)

Procedure	1. Select EU Directive (i.e. 2016/425/EEC) 2. Manufacture as per applicable international Std (i.e. EN 149, EN 166 etc. as per the product requirement) 3. Prepare Technical File as per directive and International Standard 4. Prepare samples for testing by **Notified Body (NB)** or accredited Lab acceptable to NB 5. Select Notified Body (NB) from Nando Site (link given below) 6. Select EUAR to be custodian of Technical File Other features: ▪ EUAR will maintain your Technical File and Notified Body will issue Certificate CE Mark (with NB Number) ▪ Certificate will be for 3/5 years depending on NB/ Product ▪ Address of both NB and EUAR are mentioned on certificate
NB & EU Rep	*Both NB & EUAR will be required*
Testing	*Preferably by NB or referred Lab.* *Testing to be carried our as per international standard such as EN 149, EN 166 etc*
QA/ Site Inspection	Not required

Category 3: Life at High Risk (Injury leading to death- Risk of Death)

Procedure	1. Select EU Directive (i.e. 2016/425/EEC) and 2. Manufacture as per applicable international Std (i.e. EN 149, EN 166 etc. as per the product requirement) 3. Prepare Technical File as per directive and International Standard 4. Prepare samples for testing by Notified Body or accredited Lab acceptable to NB 5. Select Notified Body (NB) from Nando Site (link given below) 6. Select EU Rep to be custodian of Technical File Other features: ▪ EU Rep will maintain your Technical File and Notified Body will issue Certificate CE Mark (with NB Number) ▪ Certificate will be for 3/5 years depending on NB / Product ▪ Annual Fee to EU Rep ▪ Address of both NB and EU rep are mentioned on certificate ▪ **Inspection of production site by NB or any nominated rep will be required** ▪ **Similarly annual surveillance will be required by NB but generally they are satisfied with ISO 9001 Certificate**
NB & EU Rep	*Both NB & EU Rep will be required*
Testing	*Preferably by NB or referred Lab.* *Testing to be carried our as per international standard such as EN 149, EN 166 etc*
QA/ Site Inspection	Yes it will be required initially and may be for annual surveillance also

3. Harmonized standards for PPEs

Applicable & related standards can be seen here:

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018XC0615(03)

4. Notified Bodies:

Approved Notified body can be selected on the **nando list** according to product:

https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=155501

5. Our Preferred EU Representatives:

a. CMC Medical Devices and Drugs Sl Spain
b. HDJ Limited-UK
*c. Cert Link Certification Services – Italy**

**For PPEs only as MoH Italy is taking lot of time in case of MD*

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