

CE CERTIFICATION FEES

FOR

MEDICAL DEVICE

## A. Guidance and Documentation Fees.

Activity	Class of Medical Device				
	1	1s/m	11a	11b	111
Guidance on MDD Requirements related to your Device	Free	Free	Free	Free	Free
Identification of Class and Harmonized Standards	Free	Free	Free	Free	Free
Preparing Technical File / Design Dossier	\$ 800	\$ 1000	\$ 1300	\$ 1500	\$ 1800
Animal Origin Devices - Technical file / Design Dossier			\$ 1500	\$ 1800	\$ 1900
Radiation Emitting Devices - TCF / Design Dossier			\$ 1600	\$ 1900	\$ 2100
Medical Software - Technical file / Design Dossier			\$ 1400	\$ 1500	\$ 1600
Support in closing NB reviewer comments	\$ 400	\$ 500	\$ 600	\$ 700	\$ 800
Label Review	\$ 100	\$ 200	\$ 200	\$ 300	\$ 300

### **Important:**

- OBL / PLM will be charged 30 % less
- Active Implants Technical file / Design Dossier starts from \$ 2200
- IVD Technical file / Design Dossier starts from \$ 1600
- Payment - 50 % advance, 30% before submission and balance after approval.
- Method of communication - Telephone / Skype / G talk.
- Language for communication – English.
- Documentation by external Cloud server.
- Minimum Timeline - 30-45 Days.
- Taxes applicable as per Government rules.
- Travelling to client location will be invoiced extra.
- Dont forget to get NB quote from us for price comparision!!!

## CONTACT US

INDIA – Bangalore

+ 91 994 591 2081

USA – Chicago

+1 630 696 1293

**B. Notified Body CE Certification Fees ( For Reference purpose ONLY)**

Class of Device	First Year Fee	
	USD	INR
Class 1	Self	Self
Class 1s/m	3700	220000
Class 11a	4750	285000
Class 11b	6200	385000
Class 111	7500	450000

**Important:**

- CE Certificate validity is five years
- Auditor travelling and Lodging additional
- Annual Surveillance Fee will be 35% of the initial year fee
- Client should be invoiced separately for surprise audit and Notified body direct audits
- Class 1 product certification can be arranged

More information Please visit

<http://www.i3cglobal.com/fees/ce-marking-fees.html>

E MAIL - [enquiry@i3cglobal.com](mailto:enquiry@i3cglobal.com)

## CONTACT US

**INDIA – Bangalore**

**+ 91 994 591 2081**

**USA – Chicago**

**+1 630 696 1293**

# Attention!!!

*Small and medium size companies*

# COST OF

# CE MARKING

WE ARE very economical