



May 1, 2020

RE: Far East suppliers Forehead IR thermometer on every street corner !

I have had 11 emails this week from “suppliers” claiming : “they sell me quality Forehead / Body thermometers at great price ! “ or this beauty : “ big order cancelled have 1000 pieces to sell “, and the real attention getter : “ have quality product with FDA OK .. “ what ?

Here are a few pieces of wisdom ; guidance ; opinion ; facts - ASK !- are you selling me a true **CLINICAL - MEDICAL - HOSPITAL GRADE NON-CONTACT INFRARED THERMOMETER ?**

*A. First and most important IF anybody labels , marks a product , displays on box or directly refers to their product being **FDA APPROVED** should NOT be trusted.*

Why ? “pursuant to 21 CFR 807.39 [ in the FDA Guidance Documents ] states clearly that ANY representation that creates an impression of official APPROVAL is misleading and constitutes misbranding.” and may be subject to civil penalties.

B. I cut right to chase with these emails and ask some very easy to answer questions [ and perhaps you too can ask these “suppliers” same/same and assure yourself of buying a real thermometer and not a fake thermometer:

>> What FDA classification was your thermometer applied under ?

Metris' THD2FE answer: “ THERMOMETER, ELECTRONIC, CLINICAL “

>> What FDA Product Code and Class is your thermometer listed as ?

Metris' THD2FE answer: PRODUCT CODE FLL CLASS 2

>> What is the FDA Regulation Number your thermometer submitted for ?

Metris' THD2FE answer : REGULATION 880.2910

>> What is your FDA PRE-Market listing number ?

The THD2FE was assigned number K121428

>> What is your FDA Owner / Operator Number ?

Metris' THD2FE answer : 10068952 and 9045429

>> What is your FDA Registration Number ?

Metris' THD2FE answer : 3015171186 and 3004026659

>> Can you give me your GUDID Number ?

Metris' THD2FE answer : 4710810452130

Simple questions- to ASSURE you are getting A CLINICAL-MEDICAL-HOSPITAL GRADE DEVICE. Our factory has had 15 years experience in the manufacture of MEDICAL devices.

Be Safe out there !

Sincerely Yours ~ Bob Ogden