

Company Letter Head

Date: 13-Apr-2024

The Office of the DCGI, CDSCO

FDA Bhavan, Kotla Marg, Mandi House

New Delhi 110002

Dear Sir/Madam,

Subject: Application for Test License for our medical device – MD12

Ref.: 20. Angioscope, Class B, Angioscope is used to visually examine the interior of a blood Vessel. As per Notice No.DCG (I/Misc./2017 (68) dated 29.06.2017.

We XYZ (company name), a leading medical technology innovator dedicated to developing angioscopes and related accessories that revolutionize patient care. We are driven by a relentless pursuit of innovation, translating groundbreaking ideas into tangible solutions that address unmet medical needs. We are based out ABC (address).

Our innovative product, Everlast Angioscopes, falls under the Class B device classification, allowing for visual examination of blood vessel interiors. These ultrathin, flexible angioscopes boast high-resolution miniature cameras at their tips. Inserted through a minute incision, they grant doctors direct visualization of the vasculature. This minimally invasive procedure offers substantial advantages. By providing a clear view, angiography facilitates the diagnosis of blockages, abnormalities, and vascular damage. This leads to more accurate diagnoses and optimized treatment plans. Furthermore, our angioscopes can be used to guide procedures like angioplasty and stent placement, enhancing their effectiveness.

In conjunction with the commencement of the manufacturing process for our innovative medical device, Everlast, we formally request a Test License to Manufacture. This license, obtained through Form MD12, would enable us to produce a limited quantity of ten (10) devices for the express purpose of conducting essential technical studies and pilot clinical trials. We have attached all relevant supporting documentation to this letter for your review.

We thank the CDSCO for considering our Test License application for Everlast. We've attached all required documents (MD12 checklist) and are committed to transparency. Should any clarification be needed, please don't hesitate to contact us. A prompt license issuance would expedite Everlast's development, allowing internal and third-party validations. Everlast has the potential to significantly improve patient care, and we're eager to collaborate with the CDSCO to bring this innovation to life.

Yours sincerely,

(Authorized person), (role),

(company name),

(email id)

(contact number)