GOVERNMENT OF KARNATAKA
DRUGS CONTROL DEPARTMENT

No. DCD/MFG/SR-805/20-21

Office of the Drugs Controller
for the State of Karnataka
Palace Road, Bengaluru - 01.
Date:

26 FEB 2021

To,
M/s. Aster Medispro Pvt. Ltd.,
S.P. 181, 10th Main, 1st Stage,
Dr. B. R. Ambedkar Industrial Estate,
Jigani, Bengaluru Rural – 560 105.

Sir,

Sub: Drugs & Cosmetics Act, 1940 and Rules 1945 – application for fresh Licence in Form MD - 5.

Ref: 1. Your application dated 09.10.2020 for fresh licence in Form MD - 5.
2. M/s. Zenith Quality Assessors Pvt. Ltd., Pune (Notified Body) Audit report File No. MFG/MD/2020/30689 & report No. MDR/91/A/1268-1, dated 12.01.2021.

****

I am to state that you are granted manufacturing licence in Form MD – 5, bearing No. MFG/MD/2021/000046, dated 17.02.2021 for the manufacture of Medical devices. The licence is valid from 17.02.2021 to 16.02.2026.

You are required to intimate the date of commencement of manufacture of the said products and to send the test reports of the first six batches of the product duly analysed at an approved laboratory.

You should comply the provisions of Drugs & Cosmetics Act and Rules, Medical Devices Rules, 2017 & Drugs (Prices Control) Order 2013 as applicable to your unit and also to the price fixed by the NPPA for the products permitted under this letter, if any.

You are requested to submit the specimen labels/cartons of the products in triplicate complying with the labelling provisions to this office for records.

26 FEB 2021

OFFICE OF THE DRUGS CONTROLLER FOR THE STATE OF KARNATAKA

Yours faithfully,

(Amaresh Tumbagi)
Additional Drugs Controller &
Licensing Authority

Copy to: NPPA for information