

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:

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.

12 6 FEB 2021

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.

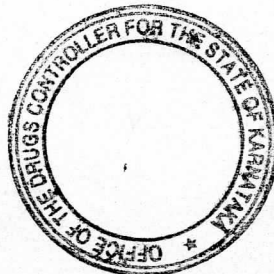
You are required to intimate the date of commencement of manufacture of the said
products and to send the test reports of the first six batches of the product duly analysed at
an approved laboratory.

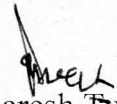
You should comply the provisions of Drugs & Cosmetics Act and Rules, Medical
Devices Rules, 2017 & Drugs (Prices Control) Order 2013 as applicable to your unit and
also to the price fixed by the NPPA for the products permitted under this letter, if any.

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

Yours faithfully,

12 6 FEB 2021




(Amaresh Tumbagi)
Additional Drugs Controller &
Licensing Authority

Copy to: NPPA for information