



सत्यमेव जयते

## FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/IVD/2023/000124

Endorsement No. 1

1. M/s Sterile Safequip And Chemicals LLP, 31, Panchratna Industrial Estate, Inside Pirana Gate, S.P. Ring Road, Village Paldi-kankaj, DaskroiAhmedabad, Ahmedabad, Gujarat (India) - 382425 Telephone No.: 9825155778 FAX: 9825155778 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s M/s Sterile Safequip And Chemicals LLP, 31, Panchratna Industrial Estate, Inside Pirana Gate, S.P. Ring Road, Village Paldi-kankaj, Daskroi, Ahmedabad, Gujarat (India) - 382425 Telephone No.: 9978655778 FAX: 9978655778

2. Details of medical device(s) [Annexed]

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

### ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:Biochemistry Analyzer Model No.:ZELLECHEM - Semi-Biochemistry Analyzer Intended Use:An analyzer intended for measuring and analyzing various biological and chemical elements of human body fluid. It is intended for in-vitro diagnostic use. Class of medical device:Class A Material of construction:MS Powder coated bottom with ABS plastic at outer covering body Dimension(if any):400 (L) X 300 (W) X 160 (H) Shelflife:NA Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):ZELLECHEM

Place:GANDHINAGAR

Date:13-Mar-24

Digitally signed by Dr. H. G. KOSHIA  
DN: cn=Dr. H. G. KOSHIA, o=Food  
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State Licensing Authority