



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

1. M/s Sterile Safequip And Chemicals LLP, 31, Panchratna Industrial Estate, Inside Pirana Gate, S.P. Ring Road, Village Paldi-kankaj, Daskroi Ahmedabad, 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	<p>Generic Name:Erythrocyte Sedimentation Rate (ESR) Analyzer Model No.:ZELLESR 10 - Input 210~230V, AC-50-60Hz, Reading Chamber- 10, Display - 4.2" Color touch screen, Loading Capacity - 20 samples per hr, Memory- 9999 sample results.,ZELLESR 20 - Input 210~230V, AC 50-60Hz, Reading Chamber - 20, Loading Capacity - 40 samples per hr, Display - 4.2" Color touch screen, Memory - 9999 sample result. Intended Use:An analyzer intended to be used to determine the erythrocyte sedimentation rate (ESR) of red blood cells in an anti-coagulated whole blood specimen. Class of medical device:Class A Material of construction:Polymer Plastic Dimension(if any):323mm(L) X196mm(W)X187mm(H) Shelflife:Nil Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):ZELLESR</p>

Place: GANDHINAGAR

Date 22-Sep-23

State Licensing Authority