



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. 2

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	<p>Generic Name:Erythrocyte Sedimentation Rate (ESR) Analyzer Model No.:ZBT-ESR DT10 - Power Supply -110-230V AC 50 HZ/60 HZ Weight -4 Kg LIS Interface - Via RS-232 & HL 7 Protocol USB Port -2 (One is for Printer & Another one is for barcode reader) Intended Use:An analyzer intended to be used to determine the erythrocyte sedimentation rate (ESR) of red blood cells in an anticoagulated whole blood specimen. It is intended for in-vitro diagnostic use. Class of medical device:Class A Material of construction:Polymer Methyl Methacrylate (PMMA) Dimension(if any):240mm(L) X330mm(W)X280mm(H) Shelflife:NA Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):ZBT- ESR</p>

Place: GANDHINAGAR

Date:13-Mar-24

Digitally signed by Dr. H. G. KOSHIA
DN: cn=Dr. H. G. KOSHIA, o=Food and Drugs Control Administration, ou=Commissioner, email=comfdca@gujarat.gov.in, c=IN
Date: 2024.03.13 22:45:17 +05'30'
State Licensing Authority