



MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

(Section 3B(2)(e) of the Pharmacy and Poisons Act, Cap 244 Laws of Kenya)

MEDICAL DEVICE REGISTRATION CERTIFICATE

This Registration Certificate is issued to

TRANSAFRICA MEDICAL SUPPLIES LTD

for distribution and sale of

BONDENT UNITS

Registration Number:	MD/2023/900
Certificate Valid Until:	13th June 2028
Registration Date:	14th June 2023
Device Category:	Class A
GMDN:	
GMDN Term:	A

Intended Purpose:

DENTAL CHAIR FOR PATIENTS TO SIT ON DURING PROCEDURES



MAH Details:

BONDENT GROUP

Manufacturing Sites :

SICHUAN BOMESIN DENTAL EQUIPMENT CO. LTD,

Device Accessories:

& Bondent Dental Chair E200A & Bondent Dental Chair E200B & Bondent Dental Chair E200C & Bondent Dental Chair S500 & Bondream CBCT 1020E & Bondream CBCT 1020S & Bondream CBCT 1020MS & Semnor Naked Eye 3D Semorr surgical microscope & G4-D Semorr surgical microscope & Wispex & Training Kit & Training Block & Stopper & Standard Gutta Percha Points & Stainless Steel Reamers & Stainless Steel K Files & Stainless Steel H Files & Stainless Steel C Files & Plugger & Platinum V.EU & Peeso Reamer & Paste Carrier & Paper Points & Micro Shaper & Micro Opener & Measure Ruler & Marc III & M3 TP & M3 T & M3 Safe Path & M3 Safe Opener & M3 Pro Gold V.3 & M3 RT & M3 Pro Gold V.2 & M3 Pro Gold V.1 & M3 Path & M3 Opener & M3 L Platinum V.2 & M3 L Platinum V.1 & M3 Immature Blue & Irrigation Needle & iRoot Pro & iRoot Apex & Hand Files Holder & Endo Wise Plus & Endo Wise & Endo Training Tooth & Endo Clean Box & Endo Box & eHeater & eFiller & Dental Simulation Practice System & CC Premium V.EU & CC Premium & CC One Plus & CC One Blue

The above Medical Device has been entered on the Record subject to the following conditions:
● The granted approvals herein are in accordance to the Laws of Kenya, Health Amendment Law 2019 and the applicant is required to adhere to the stipulated conditions.
& Actor I pro & Uni- Trans & Uni- Clear Pro & Stainless Steel Archwires & Springs & Separators & Reverse Back Archwires & Power Chain & Orthodontic Molar Band Assorted Kit & Omni SL 6th Generation & Omni MIM & O-rings & Niti Thermal Active Archwires & Niti Super Elastic & Micro Implants Handles & Micro Implants & Lingual Buttons & Ligature Ties & Innovative Aligner and Service System & Crimp Hooks & Clear Max Pro.
● The applicant of a medical device shall keep an up to date log of information of all the medical devices registered.

Device Group:

DENTAL CLINIC UNITS

Device Sub-group/Sub-sets:

& Bondent Dental Chair E200A & Bondent Dental Chair E200B & Bondent Dental Chair E200C & Bondent Dental Chair S500 & Bondream CBCT 1020E & Bondream CBCT 1020S & Bondream CBCT 1020MS & Semnor Naked Eye 3D Semorr surgical microscope & G4-D Semorr surgical microscope & Wispex & Training Kit & Training Block & Stopper & Standard Gutta Percha Points & Stainless Steel Reamers & Stainless Steel K Files & Stainless Steel H Files & Stainless Steel C Files & Plugger & Platinum V.EU & Peeso Reamer & Paste Carrier & Paper Points & Micro Shaper & Micro Opener & Measure Ruler & Marc III & M3 TP & M3 T & M3 Safe Path & M3 Safe Opener & M3 Pro Gold V.3 & M3 RT & M3 Pro Gold V.2 & M3 Pro Gold V.1 & M3 Path & M3 Opener & M3 L Platinum V.2 & M3 L Platinum V.1 & M3 Immature Blue & Irrigation Needle & iRoot Pro & iRoot Apex & Hand Files Holder & Endo Wise Plus & Endo Wise & Endo Training Tooth & Endo Clean Box & Endo Box & eHeater & eFiller & Dental Simulation Practice System & CC Premium V.EU & CC Premium & CC One Plus & CC One Blue & Actor I pro & Uni- Trans & Uni- Clear Pro & Stainless Steel Archwires & Springs & Separators & Reverse Back Archwires & Power Chain & Orthodontic Molar Band Assorted Kit & Omni SL 6th Generation & Omni MIM & O-rings & Niti Thermal Active Archwires & Niti Super Elastic & Micro Implants Handles & Micro Implants & Lingual Buttons & Ligature Ties & Innovative Aligner and Service System & Crimp Hooks & Clear Max Pro.
● A applicant shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.

Products Covered by This Entry

& Bondent Dental Chair E200A & Bondent Dental Chair E200B & Bondent Dental Chair E200C & Bondent Dental Chair S500 & Bondream CBCT 1020E & Bondream CBCT 1020S & Bondream CBCT 1020MS & Semnor Naked Eye 3D Semorr surgical microscope & G4-D Semorr surgical microscope & Wispex & Training Kit & Training Block & Stopper & Standard Gutta Percha Points & Stainless Steel Reamers & Stainless Steel K Files & Stainless Steel H Files & Stainless Steel C Files & Plugger & Platinum V.EU & Peeso Reamer & Paste Carrier & Paper Points & Micro Shaper & Micro Opener & Measure Ruler & Marc III & M3 TP & M3 T & M3 Safe Path & M3 Safe Opener & M3 Pro Gold V.3 & M3 RT & M3 Pro Gold V.2 & M3 Pro Gold V.1 & M3 Path & M3 Opener & M3 L Platinum V.2 & M3 L Platinum V.1 & M3 Immature Blue & Irrigation Needle & iRoot Pro & iRoot Apex & Hand Files Holder & Endo Wise Plus & Endo Wise & Endo Training Tooth & Endo Clean Box & Endo Box & eHeater & eFiller & Dental Simulation Practice System & CC Premium V.EU & CC Premium & CC One Plus & CC One Blue & Actor I pro & Uni- Trans & Uni- Clear Pro & Stainless Steel Archwires & Springs & Separators & Reverse Back Archwires & Power Chain & Orthodontic Molar Band Assorted Kit & Omni SL 6th Generation & Omni MIM & O-rings & Niti Thermal Active Archwires & Niti Super Elastic & Micro Implants Handles & Micro Implants & Lingual Buttons & Ligature Ties & Innovative Aligner and Service System & Crimp Hooks & Clear Max Pro.

Po Box 27663-00506
Nairobi, Kenya

Serial NO: a7639d6a97f7ce57ffec08fd91c68357
Registration Date: 14-06-2023

