



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/MD/2023/000011

1. M/s JYOTI CERAMIC INDUSTRIES PRIVATE LIMITED, 1001, 10TH FLOOR, SATGURU SHARAN, PLOT NO.150 29TH ROAD, TPS III, BANDRA (W)MUMBAI, Mumbai City, Maharashtra (India) - 400050 Telephone No.: 0253 2350120 FAX: 0253 2350023 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Jyoti Ceramic Industries Pvt. LTD., Plot C-21, Satpur, B-road, NICE, Nashik , Nashik, Maharashtra (India) - 422007 Telephone No.: 0253 - 235120 FAX: 0253 - 2350023

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: JYODENT ZIRCONIA CERAMIC DENTAL BLANKS</p> <p>Model No.: ZD9810-ZD9826 - ZD9810/12/14/16/18/20/22/24/26, IS-ZD9810-ZD9826 - IS-ZD9810/12/14/16/18/20/22/24/26, IS-TR-ZD9810-ZD9826 - IS-TR-ZD9810/12/14/16/18/20/22/24/26, IS-ETR-ZD9810-ZD9826 - IS-ETR-ZD9810/12/14/16/18/20/22/24/26, IS-CZD 9810-IS-CZD 9826 - IS-CZD9810/12/14/16/18/20/22/24/26, IS-TR-CZD 9810-IS-CZD 9826 - IS-TR-CZD9810/12/14/16/18/20/22/24/26, ZBS201415 - ZBS201415, ZBS201915.5 - ZBS201915.5, ZBS4020155 - ZBS4020155, ZBS551915.5 - ZBS551915.5, ZBS652522 - ZBS652522, IS - TR - ZBS551915.5 - IS - TR - ZBS551915.5, IS - TR - ZBS201915.5 - IS - TR - ZBS201915.5, IS - TR - ZBS401915.5 - IS - TR - ZBS401915.5, IS - ETR - ZBS551915.5 - IS - ETR - ZBS551915.5, IS - ETR - ZBS201915.5 - IS - ETR - ZBS201915.5, IS - ETR - ZBS401915.5 - IS - ETR - ZBS401915.5, IS - TR - CZBS551915.5 - IS - TR - CZBS551915.5, IS - TR - CZBS2019155 - IS - TR - CZBS2019155, ZB763812-16 - ZB763812/14/16, ZAR947512-16 - ZAR947512/14/16, ZAR885712-16 - ZAR885712/14/16, ZAR897210-26 - ZAR897210/12/14/16/18/20/22/24/26, IS-TR-ZAR897210-26 - IS-TR-ZAR897210/12/14/16/18/20/22/24/26, IS-ETR-ZAR897210-26 - IS-ETR-ZAR897210/12/14/16/18/20/22/24/26</p> <p>Intended Use: The intended use of dental blanks is that the blanks are to be used by end user to manufacture non-active, long term replacement for dental restoratives.</p> <p>Class of medical device: Class B</p> <p>Material of construction: ZIRCONIUM OXIDE</p> <p>Dimension(if any): ZD9810-9826, IS-ZD9810-26, IS-TR-ZD9810-26, IS-ETR-ZD 9810-26, IS-CZD 9810-26, IS-TR-CZD 9810-26, ZBS201415, ZBS201915.5, ZBS4020155, ZBS551915.5, ZBS652522, IS - TR - ZBS551915.5, IS - TR - ZBS201915.5, IS - TR - ZBS401915.5, IS- ETR- ZBS551915.5, IS- ETR-ZBS201915.5, IS- ETR-ZBS401915.5, IS-TR-CZBS551915.5, IS-TR-CZBS2019155, ZB763812-16, ZAR947512-16, ZAR885712-16, ZAR897210-26, IS-TR-ZAR897210-26, IS-ETR-ZAR897210-26</p> <p>Shelflife: TILL IN USE</p> <p>Sterile or Non sterile: Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): JYODENT ZIRCONIA CERAMIC DENTAL BLANKS</p> |
|---|---|

Place:

Date 04-Jan-23

**Mukund
Manikrao
Donglikar**

Digitally signed by
Mukund Manikrao
Donglikar
Date: 2023.01.04
14:34:20 +05'30'

State Licensing Authority