

FORM MD-15

[See sub-rule (1) of rule 36]

Licence to Import Medical Device

Licence No. : IMP/MD/2021/000586

1. M/s EVENT MEDI SYSTEMS, 218, VISHAL TOWER, DISTRICT CENTRE, JANAKPURI, NEW DELHI , West Delhi, Delhi (India) - 110058 Telephone No.: 01145804568 FAX: 01125558455 is hereby licenced to import the medical device(s) manufactured by overseas manufacturer having manufacturing site as specified below.

S.No	Name and Address of Manufacturer	Name and Address of Manufacturing Site
1	Legal Manufacturing Site : M/s Biometrix Ltd, 4 Kiryat Mada, Jerusalem 9145000, Country: Israel Telephone No.: 972-2-5861241 FAX: 972-2-5861322 E-Mail : mail@biometrixmedical.com	Actual Manufacturing Site : M/s Biometrix S.R.O., Vicenzy 16, Samorin 93101 , Country: Slovakia Telephone No.: 421 31 285 1810 FAX: 421 31 285 1810 E-Mail : mail@biometrixmedical.com

3. Details of medical device(s):

S.No	Medical Device Details
1	<p>1. Generic Name :PTCA Accessories Kit</p> <p>2. Brand Name(if registered under the Trade Marks Act, 1999) :Angio-Line</p> <p>3. Class of Medical Device :Class A</p> <p>4. Shelf Life :3 Years</p> <p>5. Sterile/Non-sterile: Sterilized</p> <p>6. Intended Use : PTCA Accessories Kit (Y Connector Kit) is intended to be used in angioplasty procedures. It is intended to maintain hemostasis during the introduction , use and withdrawal of diagnostic devices used in angioplasty procedures. it can be connected to perfusion sets/catheters to infuse contrast medium etc.</p> <p>7. Material of Construction: Poly Carbonate (PC) & Stainless Steel</p> <p>8. Dimension: N.A</p> <p>9. Model No. :BQ-1906 - Angio-Line PTCA Accessories Kit,BQ-1905 - Angio-Line PTCA Accessories Kit,BQ-0905 - Angio-Line PTCA Accessories Kit,BQ-0906 - Angio-Line PTCA Accessories Kit,BQ-2905 - Angio-Line PTCA Accessories Kit,BQ-0805 - Angio-Line PTCA Accessories Kit,BQ-Y0805 - Angio-Line PTCA Accessories Kit,BQ-X0805 - Angio-Line PTCA Accessories Kit,BQ-0010 - Angio-Line PTCA Accessories Kit,BQ-0015 - Angio-Line PTCA Accessories Kit,BQ-0020 - Angio-Line PTCA Accessories Kit,BQ-0504 - Angio-Line PTCA Accessories Kit,BQ-0505 - Angio-Line PTCA Accessories Kit,BQ-0506 - Angio-Line PTCA Accessories Kit,BQ-0602 - Angio-Line PTCA Accessories Kit,BQ-0701 - Angio-Line PTCA Accessories Kit,BQ-0702 - Angio-Line PTCA Accessories Kit</p>

4. The authorised agent M/s EVENT MEDI SYSTEMS, 218, VISHAL TOWER, DISTRICT CENTRE, JANAKPURI, NEW DELHI , West Delhi, Delhi (India) - 110058 Telephone No.: 01145804568 FAX: 01125558455 will be responsible for the business activities of the overseas manufacturer, in India in all respects.
5. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

Place: New Delhi

Central Licensing Authority

