

Registration Certificates issued for the Medical Devices along with their Manufacturing sites and Indian Authorized

Agents from December 2016 to till Date

S.No.	Name of Indian Agent	Name of Manufacturer	Name of the Device	File No.	R. C. No.	Date of Issue	Validity of the Registration Certificate
1.	M/s. Kalyx India Healthcare Pvt. Ltd., Old no. 12, New No. 20, 1 st Floor, M-Block, 8 th Street, Anna Nagar (East), Chennai-600102	M/s. Dieter Marquardt Medizintechnik GmbH., having manufacturing site at Robert-Bosch-Str. 1, D- 78549 Spaichingen-Germany and its medical device	<ol style="list-style-type: none"> 1. Orthopaedic Trauma Implants (Screws)- Non-sterile (Titanium) 2. Orthopaedic Trauma Implants (Plates)- Non-sterile (Titanium) 3. Orthopaedic Trauma Implants (Screws)- Non-Sterile (Stainless Steel) 4. Orthopaedic Trauma Implants (Plates)- Non-sterile (Stainless Steel) 5. Plates & Screws (Hip)- Non-sterile (Stainless steel) 6. Orthopaedic Trauma Implants- Intramedullary Implants (Screws)-sterile (Titanium) 7. Orthopaedic Trauma Implants- Intramedullary Implants (Nails)-sterile (Trauma) 	31-1658-MD/2015-DC	MD-1658	05-12-2016	21-11-2016- to 20-11-2019
2.	M/s. Covidien Healthcare India Pvt. Ltd., # 156, "Doshi Towers", 6 th Floor, Poonamallee High Road, Kilpauk, Chennai-600010	M/s. Covidien LLC, 15 Hampshire Street, Mansfield, MA USA 02048 having manufacturing premises at M/s. Covidien Manufacturing solutions, S.A., Edificio B20, Calle #2 Zona Franca, Coyol, Alajuela, Costa Rica	<ol style="list-style-type: none"> 1. Mahurkar Elite Acute Dual Lumen Catheter Kits, Catheter 2. Mahurkar Elite Acute Triple Lumen Catheter Kits, Catheter 	31-1228-MD/2012-DC(Re. Reg.01) (End. 01)	MD-1228	05-12-2016	31-05-2018
3.	M/s. Osstem Implant India Pvt.	M/s. Osstem Implant Co. Ltd., having	Titanium Mesh (Barrier, Intra-Oral, Non-absorbable for tissue regeneration)	31-1700-MD/2015-DC	MD-1700	06-12-2016	12-04-2016 To 31-03-2019

	Ltd., Office No. 306, 3 rd Floor, A Wing, "Sagar Tech Plaza" Sakinaka, Andheri- Kurla Road, Andheri (E), Mumbai- 400072.	manufacturing premises at 66-16, Bansong-ro 513 Beon-gil, Haeundae-gu, Busan, Korea.		(End. 01)			
4.	M/s Nipro India Corporation Private Ltd., New No. 167, Old No. 131, Yes dee House, 1st Floor, Valluvar kottam High Road, Nungambakkam, Chennai-600034	M/s. Nipro Corporation, 3-9-3, Honjo Nishi Kita -Ku, Osaka 531-8510, Japan having manufacturing premises at M/s. Nipro Medical Industries Ltd., 2-19-64, Matsubara, Tatebayashi-Shi, Gumna: 374-8518 Japan	Nipro Spinal Needle, Spinal Needle	31-1078-MD/2012-DC (Re. Reg. 01) (End. 01)	MD-1078	26-12-2016	15-05-2019
5.	M/s. Terumo India Pvt. Ltd., 117/3D & 117/3C (Part 1-C), Padmavathi Gardens, Numbal, Velapanchavadai, Post, Thiruverkadu, Chennai-77	M/s. Terumo (Philippines) Corporation, # 124 East Main Avenue, Laguna Tecnopark, Binan, Laguna, Philippines having manufacturing premises at M/s. Terumo (Philippines) Corporation, # 124 East Main Avenue, Laguna Tecnopark, Binan, Laguna, Philippines	<ol style="list-style-type: none"> 1. Surguart2® safety Hypodermic Needle, Hypodermic Needle 2. Surguart3® safety Hypodermic Needle, Hypodermic Needle 	31-1470-MD/2014-DC	MD-1470	30-12-2016	01-12-2016 to 30-11-2017
6.	M/s. Stryker India Pvt. Ltd., Khewat No. 122, Kahta No. 157, Mustakil No. 98, Kila No. 6, 7, 8/1, 13/1 Village Bhondsi, District	M/s. Howmedica Osteonics Corporation, 325 Corporate Drive Mahwah, New Jersey 07430, USA Having manufacturing premises at	Modular Dual Mobility Insert (MDMCoCrLiner), Hip replacement implant component- Liner	31-180-MD/2006-DC(Re. Reg.03) End-01	MD-180	05-01-2017	30-04-2019

	Gurgaon, Haryana	M/s. Stryker Ireland Ltd., IDA Industrial Estate, Carrigtwohill Co., Cork, Ireland					
7.	M/s. Cambridge Medical India Pvt. Ltd., First Floor, F- 2, New No. 108, old no. 3, 86 th Street, 18 th Avenue, Ashok Nagar, Chennai-600083, Tamil Nadu, India	M/s. Bioplate, Inc., having manufacturing premises at 3643 Lenawee Avenue, Los Angeles, California- 90016 USA	1. Plates, Screws, Bio Mesh, Maxillofacial System- Titanium (Non Sterile) 2. Plates, Screws, Bio Mesh, ZIP Implants , Neurosurgery Cranial Fixation System- Titanium (Non Sterile)	31-1733- MD/2015-DC	MD- 1733	05-01-2017	16-12-2016 to 15-12-2019
8.	M/s. Merit Medicals Systems India Pvt. Ltd., Unit No, 206-207, H.M. Geneva House 2 nd Floor, No. 14, Cunningham Road Bangalore- 560052	M/s. Merit Medical Systems Inc., 1600 West Merit Parkway, South Jordan, Utah 84095, USA having manufacturing premises at M/s. BioSphere Medical, S.A. Pare des Nations- Paris Nord 2, 383 rue de la Belle Etoile, 95700 Roissy EN France	Bearing TM nsPVA Embolization particles, Embolic Microspheres (Non spherical polyvinyl Alcohol)	31-1360- MD/2013-DC	MD- 1360	05-01-2017	16-12-2016 to 15-12-2019
9.	M/s. Zimmer India Pvt. Ltd., 14th Floor, Tower-5B DLF Cyber Terraces, DLF Cyber City, Gurgaon-122002, Haryana, India	M/s. Zimmer Inc., having manufacturing premises at 1800 West Center Street, Warsaw Indiana 46580, USA	Persona the Personalized knee System Stem Extension, Stem Extension	31-170-MD/2006- DC (End. 01)	MD-170	17-01-2017	31-07-2018
10.	M/s. Vardhman Medicare Pvt. Ltd. L-90/164, 2 nd Floor, Street No. 7,	M/s. Rocket Medical Plc., having manufacturing premises at 2-4 Sedling Road, wear Industrial	1. Rocket IPC, Rocket IPC Insertion Set 2. Rocket, Rocket Thoracentesis Catheter	31-1621- MD/2014-DC	MD- 1621	25-01-2017	01-01-2017 to 31-12-2019

	Mahipalpur Extn, New Delhi-110037	Estate, Washington, Tyne and Wear, NE38 9BZ, United Kingdom	<ol style="list-style-type: none"> 3. Rocket, Rocket Multipurpose Needle 4. Rocket, Rocket Thoracic Catheter 5. Rocket, Rocket Disposable Ultrasound Needle Guide 6. Rocket, Rocket Seldinger Chest Catheter Drainage Kit 7. Rocket, Rocket Blunt dissection chest drainage insertion pack 8. Rocket, Rocket HSG Sonohystogram Catheter 9. Rocket, Rocket Embryo Transfer Set 10. Rocket, Rocket Needle 11. Rocket, Rocket KCH Fetal Bladder Drainage 				
11.	M/s. Epsilon Eye Care Pvt. Ltd., Ground Floor 49, Palihil-3, Tithal Road, Valsad, Taluka: Valsad	M/s. Medennium Inc., 13 avenue de Montrouge Esc. 6 92340 Bourg la Reine, France having manufacturing premises at M/s. Medennium Inc., 9 Parker Suite 150, Irvine, CA 92618 USA	<ol style="list-style-type: none"> 1. Matrix, Acrylic®/Matrix Acrylic ®/ Aurium, Intra ocular lens 2. Matrix, Acrylic®/Matrix Acrylic ®/ Aurium, Intra ocular lens 3. Medennium Phakic Lens, Intra ocular lens 	31-15-MD/2016- DC	MD-15	16-02-2017	16-02-2017 to 31-01-2020

12.	M/s. Covidien Healthcare India Pvt. Ltd., No. 156, "Doshi Towers", 6 th Floor, Poonamallee High Road, Kilpauk, Chennai-600010	M/s. Mirco Therapeutics, Inc. d/b/a ev3 Neurovascular, having manufacturing premises at 9775 Toledo Way, Irvina, CA 92618 USA	Pipeline™ Flex Embolization Device, Embolization Device	31-51 (A)-MD/2016-DC (Re. Reg.03) (End.03)	MD-51 (A)	24-03-2017	30-06-2018
13.	M/s. Sandor Medicaids Pvt. Ltd., D. No. 8-2-326/5, Ground Floor, Road No. 3, Banjara Hills, MCH Circle- 10 Mandal, Hyderabad-500034	M/s. ULURU Inc., 4452 Beltway Drive, Addison TX, 75001, USA, having manufacturing premises at M/s. Anteco Pharma LLC, 925 Development Drive, Lodi, Wisconsin 53555, USA	Altrazeal® Transforming Powder Dressing, Transforming Powder Dressing	31-1703-MD/2015-DC	MD-1703	26-05-2017	16-05-2017 to 15-05-2020
14.	M/s. Modi Mundi pharma Pvt. Ltd., A-81 First Floor, Okhla Industrial Area Phase-II, New Delhi-110020	M/s. Anika Therapeutics, Inc., having manufacturing premises at 32 Wiggins Avenue, Bedford MA 01730 USA	Monovisc, Cross linked sodium hyaluronate 22mg/ml	31-1702-MD/2015-DC	MD-1702	03-08-2017	15-07-2020
15.	M/s. Venus Medical Products, 388 Sant Nagar East of Kailash, New Delhi-110065	M/s. Lanstec (Barbados) Inc. , having Manufacturing premises at Airport commercial center, Pilgrim Road, Christ Church BB 17029.	Softec I, Softec HD, Tetraflex HD, SBL-3, Hydrophilic Acrylic IOL	31-1111-MD/2012-DC (Re. Reg. 01)	MD-1111	21-08-2017	03-08-2020