

**Statement Indicating Status on Grant of Approval by CLAA for Manufacture of Notified Medical Devices**

**(Jan. 2013 up to till date)**

<b>S. No.</b>	<b>Name of the Manufacturer</b>	<b>Product Licenced by CLAA</b>	<b>Manufacturing Licence No. &amp; Validity</b>
1.	M/s. Polymer Technologies International (EOU) Block No. 310/C, Village of Dabhasa, Tal. Padra, Dist. Vadodara – 391440, Gujarat	1. Foldable Hydrophobic Yellow Intraocular Lens (Sterile)	Mfg Lic in Form 28 vide no. G/1321 ( valid from 18-12-2009 to 17-12-2014)
2.	M/s. Aurolab, No. 1, Sivagangai MAIN Road, Verrapanjan, Madurai – 625020	1. US 863 UV (Poly Hydroxy Ethyl Methacrylate)	Mfg Lic in Form 28 vide no. TN00002501 ( valid from 11-08-2009 to 10-08-2014)
3.	M/s. Meril Life Sciences Pvt. Ltd., Survey NO. 135/2a, Near G.M. Bilakhia Stadium, Muktannad Marg, Chala, AT & Post-Vapi, Tal-Pardi, Dist-Valsad - 396191, Gujarat	1. Rx PTCA Balloon Dilataion Catheter/ Mozec™ NC (Sterile) 2. Rx PTCA Balloon Dilataion Catheter/ Mozec™ NC (Non-Sterile) 3. Biodegradable Polymer based Sirolimus Eluting Coronary Stent System/ Biomime Aura™ Sirolimus Eluting Coronary Stent System	Mfg Lic in Form 28 vide no. G/28/1273 ( valid from 20-06-2008 to 19-06-2013)
4.	M/s. Invent Bio-Md Pvt. Ltd., 109, Surat Special Economic Zone, Diamond Park, GIDC Sachin, Gujarat – 394230	1. NOVA VIDA CHROME-Sirolmus Eluting Coronary Stent System 2. NOVA Matrix™ 3. Passage/ 3-WAY Stop Cock & 2 Port Manifold/ 3 Port Manifold 4. Proaccess/ Introducer Sheath 5. Floater/ Pressure Monitoring Line 6. Performer/ Hemostasis Y-Connector with Blunt Introducer & Totque 7. Angitrix/ PTCA Custom Kit 8. Marathon-Marathon <sup>CTO+</sup> / PTCA Guidewire 9. Guider/ Angiography Guidewire	Mfg Lic in Form 28 vide no. G/28/1306 ( valid from 20-06-2009 to 19-06-2014)

5.	M/s. Bio-Med Healthcare Products Pvt. Ltd., 30, DLF Industrial Estate-1, Faridabad, Haryana-121003	<ol style="list-style-type: none"> <li>1. Bio-Flon (I.V. Cannula with wings &amp; Injection Port)</li> <li>2. Bio-Can (I.V. Cannula with wings &amp; without Injection Port)</li> <li>3. Bio-On (I.V. Cannula without Port &amp; without wings)</li> <li>4. Neo-Kath (I.V. Cannula with small wings &amp; without Injection Port)</li> <li>5. Solidor (I.V. Cannula with port &amp; without wings)</li> <li>6. Bel-Flon (I.V. Cannula with wings &amp; Injection Port)</li> <li>7. Maxima (I.V. Cannula with Suturrable wings &amp; snap fit Port)</li> <li>8. Euro-Flon (I.V. Cannula with wings &amp; Injection Port)</li> <li>9. Euro-Can (I.V. Cannula with wings &amp; without Injection Port)</li> <li>10. Venax-2 (I.V. Cannula with wings &amp; Injection Port)</li> <li>11. Venax-1 (I.V. Cannula with wings &amp; without Injection Port)</li> <li>12. Gren-Flon (I.V. Cannula with wings &amp; Injection Port)</li> <li>13. ComCaset P (I.V. Cannula with protective chamber)</li> <li>14. Vagon + (I.V. Cannula with wings &amp; Injection Port)</li> </ol>	Mfg Lic in Form 26 vide no.651-B (H) ( valid from 25-07-2012 to 24-07-2017)
6.	M/s. Sterimed Medical Devices (P) Ltd., 38 Km. Stone Delhi-Rohtak Highway Bahadurgarh (Haryana)	Norta (Foley Balloon Catheters)	Mfg Lic in Form 28 vide no.661-B (H) ( valid from 23-06-2008 to 22-06-2013)
7.	M/s. TTK Healthcare Ltd., (Ortho Division), No 290, SIDCO Industrial Estate, Ambattur, Chennai – 98, Tamilnadu	<ol style="list-style-type: none"> <li>1. Stem (Sterile)</li> <li>2. Adapter (Sterile)</li> <li>3. Screw (Sterile)</li> <li>4. Bi-Polar Prosthesis (Sterile)</li> </ol>	Mfg Lic in Form 28 vide no.TN00002456 ( valid from 13-07-2009 to 12-07-2014)
8.	M/s. Vertias Bioeventions Pvt. Ltd., Plot No. 5305, Phase-IV, G.I.D.C., Vapi-396191, Gujarat	Enovo (Everolimus ELUTINMG Coronary Stent System)	Mfg Lic in Form 28 vide no G/28/1379 ( valid upto 21-07-2016)
9.	M/s. Sahajanand Medical Technologies Pvt. Ltd., Plot No. 33, 34, 35, 52, 53, Surat Special Economic Zone, Sachin, Surat – 394230, Gujarat	<ol style="list-style-type: none"> <li>1. EveroFlem™ (Everolimus Elutig Cobalt Chromium Coronary Stent System (EES-1)</li> <li>2. Everopro™ (Everolimus Eluting Cobalt Chromium Coronary Stent System (EES-2)</li> </ol>	Mfg Lic in Form 28 vide no G/28/1385 ( valid upto 28-08-2016)

10.	M/s. Hindustan Surgical, 749/2, Sarali Pithai Road, Village-Pithal, Taluka- Kathal, Distt. Kheda 387630, Gujarat	<ol style="list-style-type: none"> <li>1. Sterile Disposable Single use Scalp Vein Sets</li> <li>2. Sterile Disposable Single use Nelatone Catheter</li> <li>3. Sterile Disposable Single use Gibbon Catheter</li> <li>4. Sterile Disposable Single use Male External Catheter</li> <li>5. Sterile Disposable Single use Suction Catheter</li> <li>6. Sterile Disposable Single use Urethral Catheter</li> <li>7. Sterile Disposable Single use Nasal Oxygen Catheter</li> <li>8. Sterile Disposable Single use Closed Wound Suction Set</li> <li>9. Sterile Disposable Single use (Chest Drainage Catheter) Thoracic Catheter</li> <li>10. Sterile Disposable Single use Yankur Suction Set</li> <li>11. Sterile Disposable Single use Infant Feeding Tube</li> <li>12. Sterile Disposable Single use Umbilical Catheter</li> <li>13. Sterile Disposable Single use Ryles Tube Catheter</li> <li>14. Sterile Disposable Single use Levins Tube Catheter</li> <li>15. Sterile Disposable Single use Peritoneal Dialysis Set (Catheter)</li> <li>16. Sterile Disposable Single use Infant Feeding Tube (Catheter)</li> </ol>	Mfg Lic in Form 28 vide no G/28/1420 ( valid from 06-06-2012 upto 05-06-2017)
11.	M/s. Sky Surgicals Plot No. G-1950/2, Almighty Gate, Lodhika, G.I.D.C Metoda- 360021, Dist. Rajkot (Gujarat)	<ol style="list-style-type: none"> <li>1. Bone Screws</li> <li>2. Bone Plate</li> <li>3. Nail for Tibia/Humerous/Femur/Supracondular</li> <li>4. Hip Fixitaon Implants</li> <li>5. Spine Implants</li> <li>6. Arthroscopy Implants</li> <li>7. Locking Systems</li> <li>8. Maxillofacia Implants</li> <li>9. Wire &amp; Pins</li> </ol>	Mfg Lic in Form 28 vide no G/28/1342 ( valid from 30-12-2011 upto 29-12-2016)
12.	M/s. Suture India Pvt. Ltd., 13 <sup>th</sup> cross, 4 <sup>th</sup> Phase, Peenya Industrial Area, Bangalore - 560058	<ol style="list-style-type: none"> <li>1. Trulene Mesh (Sterile Polypropylene Mesh)</li> </ol>	Mfg Lic in Form 28 vide no KTK/28/401/2012 ( valid from 18-05-2012 upto 17-05-2017)
13.	M/s. Invent Bio-Med Pvt. Ltd., 109, Surat Special Economic Zone, Diamond Park, GIDC, Sachin, Gujarat – 394230	<ol style="list-style-type: none"> <li>1. NOVA VIDA CHROME Sirolimus Eluting Coronary Stent System</li> </ol>	Mfg Lic in Form 28 vide no G/28/1306 ( valid from 20-06-2009 upto 19-06-2014)

14.	M/s. Sahajanad Medical Technologies Pvt. Ltd., Plot No. 168/96/A, Dabhel Industrial Co-Operative Society Ltd., Village-Dabhel Daman (U.T) – 396210	1. Supraflex™ - Cobalt Chromium Sirolimus Eluting Coronary Stent System	Mfg Lic in Form 26 vide no DD/537 ( valid from 16-05-2012 upto 15-05-2017)
15.	M/s. Aurolab, No. 1, Sivagangai Main Road, Veerapanjan, Madurai – 625020	863UV (Poly Hydroxy Ethyl Methacrylate)	Mfg Lic in Form 28 vide no TN00002501 ( valid from 11-08-2009 upto 10-08-2014)
16.	M/s. Teleflex Medical Pvt. Ltd., R.S. No. 23, Thirubuvanai, Mannadipet Commune, Puducherry – 605107	1. Folley Balloon Catheters	Mfg Lic in Form 26 vide no 07222013 ( valid from 30-07-2012 upto 29-07-2017)
17.	M/s. Mesco Surgicals 4/5, Khodiyar Ware House Estate, Behind Mahalaxmi Mill, Narol Ahmedabad, Gujarat 382405	<ol style="list-style-type: none"> <li>1. Transfusion</li> <li>2. Gastroentology</li> <li>3. Paediatric</li> <li>4. Paediatric</li> <li>5. Urology</li> <li>6. Anasthesia</li> <li>7. Urology</li> <li>8. Gastroentology</li> <li>9. Surgergy</li> <li>10. Gastroentology</li> </ol>	Mfg Lic in Form 28 vide no. G/28/1375 ( valid upto 12-06-2016)

<b>18.</b>	M/s. Blue Neem Medical Devices Pvt. Ltd., No. 1, Survey No. 83/2, Doddamma Industrial Estate, Hulimavu, Bannerghatta Road, Bangalore – 560076	<ol style="list-style-type: none"><li>1.PCN Catheter</li><li>2. PCN Catheter with Suture</li><li>3. PCN Catheter with Needle</li><li>4. Malecot Catheter</li><li>5. Suprapubic Drainage Catheter Set</li><li>6. Suprapubic Catheter</li><li>7. Ureteral Catheter Open End</li><li>8. Ureteral Catheter Closed End</li><li>9. Dual lumen Catheter</li><li>10. Ureteral Catheter Cone TIP</li><li>11. Re-Entry Malecot Catheter</li><li>12.NBDC Catheter</li><li>13. ABCESS Drainage Catheter</li><li>14.PTBD Catheter</li><li>15.Ureteral Balloon Catheter</li><li>16.Internal External Drainage Catheter</li><li>17.External Internal Catheter</li><li>18. Biliary Internal Catheter</li><li>19. IUI Catheter</li><li>20. Nephrostomy Catheter Set</li><li>21. CI Catheter Male</li><li>22.CI Cateheter Female</li></ol>	Mfg Lic in Form 28 vide no. KTK/28/407/2009 (valid from 18-02-2013 upto 17-02-2018)
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19.	M/s. Biotech Vision Care Pvt. Ltd., Plot No. 555, 556, 557 Khatraj-Vadsar Road, Tal. Kalol Distt. Gandhinagar, Gujarat	<ol style="list-style-type: none"> <li>1. PMMA Intra Ocular Lens (Sterile) – Bio Vision</li> <li>2. Natural Yellow Aspheric Hydrophilic Acrylic Foldable Intra Ocular Lens (Sterile) – Eyecryl</li> <li>3. Hydrophilic Acrylic Foldable Intra Ocular Lens with Delivery System (Sterile) – Eyecryl Plus</li> <li>4. Diffractive-Refractive Multifocal Hydrophilic Acrylic Foldable Intra Ocular Lens with Delivery System (Sterile) – Eyecryl ACTV</li> <li>5. Hydrophilic Acrylic Foldable Intra Ocular Lens with Hydrophobic Surface with Delivery System (Sterile) – Eyecryl Plus</li> <li>6. Diffractive-Refractive Multifocal Hydrophobic Acrylic Foldable Intra Ocular Lens with Delivery System (Sterile) – Eyecryl ACTV</li> <li>7. Hydrophobic Acrylic Foldable Intra Ocular Lens with Delivery System (Sterile) – Eyecryl Plus</li> <li>8. Natural Yellow Hydrophobic Acrylic Foldable Intra Ocular Lens with Delivery System (Sterile) – Eyecryl Plus</li> <li>9. Aspheric Hydrophobic Acrylic Foldable Intra Ocular Lens with Delivery System (Sterile) – Eyecryl Plus</li> <li>10. Natural Yellow Aspheric Hydrophobic Acrylic Foldable Intra Ocular Lens (Sterile) – Eyecryl Plus</li> </ol>	Mfg Lic in Form 26 vide no G/1298 ( valid from 04-04-2009 upto 03-04-2014)
20.	M/s. Multi Medics Plot No. 28, HPSIDC, Phase-III, Baddi, Distt. Solan, HP – 173205	<ol style="list-style-type: none"> <li>1. M 'Sure - S</li> <li>2. M 'Sure – Cr</li> <li>3. Stream – S</li> <li>4. Stream – Cr</li> <li>5. Tapper – S</li> <li>6. Tapper – Cr</li> <li>7. MasterStent – S</li> <li>8. MasterStent – Cr</li> <li>9. MyStent – S</li> <li>10. MyStent – CR</li> </ol>	Mfg Lic in Form 28 vide no MB/10/836 ( valid upto 21-01-2016)
21.	M/s. Poly Medicure Ltd., Plot No. 115-116, Sector-59, HSIDC Industrial Area, Ballabgarh, Distt. – Faridabad, Haryana – 121004	<ol style="list-style-type: none"> <li>1. Med8 Easy-Access</li> <li>2. Ago Cannula Con Port D' Iniezone ED Alette</li> <li>3. Ago Cannula Con Alette Senza Port D' Iniezione</li> <li>4. Labor Import</li> <li>5. Labor Import</li> <li>6. Polyneo Adva</li> <li>7. Polyneo Plus</li> </ol>	Mfg Lic in Form vide no 627-B(H) (valid from 06-03-2011 upto 05-03-2016)

22.	M/s. Meril Life Sciences Pvt. Ltd., Survey No. 135/2a, Near G.M. Bilakhia Stadium Muktanand Marg, Chala AT & Post-Vapi, Tal-Pardi, Dist-Valasad – 396191, Gujarat	<ol style="list-style-type: none"> <li>1. Mozec™ PTA Balloon Dilataion Catheter/ Percutaneous Translumnal Angioplasty Balloon Dilataion (OTW – 120cm &amp; 150 cm)</li> <li>2. Mozec™ PTA Balloon Dilataion Catheter/ Percutaneous Translumnal Angioplasty Balloon Dilataion (OTW – 80cm &amp; 135 cm)</li> <li>3. Mozec™ PTA Balloon Dilataion Catheter/ Percutaneous Translumnal Angioplasty Balloon Dilataion (RX – 80 cm &amp; 150 cm)</li> </ol>	Mfg Lic in Form 28 vide no G/28/1273 valid upto 19-06-2013)
23.	M/s. Aurolab, No. 1, Sivagangai MAIN Road, Verrapanjan, Madurai – 625020	<ol style="list-style-type: none"> <li>1. Aurolens Toric/ Poly methyl methacrylate</li> <li>2. Aurovue-EV Toric/ Hydrophobic foldable acrylic</li> </ol>	Mfg Lic in Form 28 vide no TN00002501(valid from 11-8-2009 valid upto 10-8-2014)
24.	M/s. Mediplus (India) ltd., 1261-1262, MIE Part-B, Bahadurgarh, Dist Jhahhar (Haryana)- 124507	Fortune Medical	Mfg Lic in Form vide no 646 B(H) ( valid upto 31-05-2017)
25.	M/s Hindustan Syringes & Medical Devices Ltd., 174, Sector-25, Ballabhgarh, Faridabad – 121004, Haryana	<ol style="list-style-type: none"> <li>1. Scalpvan (Scalp Vein Infusion Set)</li> <li>2. Unolok(Scalp Vein Infusion Set)</li> <li>3. Select</li> <li>4. Unolok+</li> <li>5. Select Prevent</li> <li>6. Vaku-8</li> <li>7. Vaku-8+</li> </ol>	Mfg Lic in Form vide no 636 B(H) ( valid from 30-08-2011valid upto 29-08-2016)
26.	M/s. Sharma Pharmaceuticals Pvt. Ltyd., 444, GIDC Esatte, Waghodia Distt. Vadodara - 391760	<ol style="list-style-type: none"> <li>1. SPCPL, Sharma, Madison, King Ortho, Madison Ortho/ Locked Plates</li> <li>2. SPCPL, Sharma, Madison, King Ortho, Madison Ortho/ Locked Screws</li> <li>3. SPCPL, Sharma, Madison, King Ortho, Madison Ortho/ Bone Plates (Non-Locking)</li> <li>4. SPCPL, Sharma, Madison, King Ortho, Madison Ortho/ Bone Screws (Non-Locking)</li> <li>5. SPCPL, Sharma, Madison, King Ortho, Madison Ortho/ Inter-Locking Nails, Accessories</li> <li>6. SPCPL, Sharma, Madison, King Ortho, Madison Ortho/ Locking Bolts</li> <li>7. SPCPL, Sharma, Madison, King Ortho, Madison Ortho/ Oral Maxillo Facial Implants (Plates)</li> <li>8. SPCPL, Sharma, Madison, King Ortho, Madison Ortho/ Oral Maxillo Facial Implants (Screws)</li> <li>9. SPCPL, Sharma, Madison, King Ortho, Madison Ortho/ Spinal Implants</li> <li>10. SPCPL, Sharma, Madison, King Ortho, Madison Ortho/ Arthro-Scopy Implants, Pins &amp; Wires</li> </ol>	Mfg Lic in Form vide no G/28/1302 ( valid upto 30-05-2014)

27.	M/s. Meril Life Sciences Pvt. Ltd., Survey NO. 135/2a, Near G.M. Bilakhia Stadium, Muktannad Marg, Chala, AT & Post-Vapi, Tal-Pardi, Dist-Valsad - 396191, Gujarat	<ol style="list-style-type: none"> <li>1. Rx PTCA Balloon Dilataion Catheter/ (Rapid exchange Percutaneous Transluminal Coornary Angioplasty Balloon Dilatation Catheter)/ Xpedient™ (Sterile)</li> <li>2. Rx PTCA Balloon Dilataion Catheter/ (Rapid exchange Percutaneous Transluminal Coornary Angioplasty Balloon Dilatation Catheter)/ Xpedient™ (Non-Sterile)</li> <li>3. Rx PTCA Balloon Dilatation Catheter (Rapid exchange Percutaneous Transluminal Coornary Angioplasty Balloon Dilatation Catheter)/ Mozec™ (Sterile)</li> <li>4. Rx PTCA Balloon Dilatation Catheter (Rapid exchange Percutaneous Transluminal Coornary Angioplasty Balloon Dilatation Catheter)/ Mozec™ (Non-Sterile)</li> </ol>	Mfg Lic in Form 28 vide no. G/28/1273 ( valid from 20-06-2008 to 19-06-2013)
28.	M/s. Nano Therapeutics Private Limited, D-54/2 Hoziwala Industrial Estate, Sachin, Surat, Gujarat- 394230	<ol style="list-style-type: none"> <li>1. Xpirator Thrombus Aspiration Catheter/ Thrombus Aspiration Catheter</li> </ol>	Mfg Lic in Form 28 vide no. G/28/1395 ( valid up to 11-12-2016)
29.	M/s. Sharma Pharmaceuticals Pvt. Ltyd., 444, GIDC Esatte, Waghodia Distt. Vadodara - 391760	<ol style="list-style-type: none"> <li>1. SOSPL, Sharma Ortho, Sharma/ Inter-Locking Nails, Locking Bolts &amp; Accessories</li> <li>2. SOSPL, Sharma Otrtho and Sahrma/ Oral Maxillo FACIAL Implants (Plates &amp; Screws)</li> <li>3. SOSPL, Sharma Otrtho and Sahrma/ Locked Plates &amp; Locked Screws</li> <li>4. SOSPL, Sharma Otrtho and Sahrma/ Bonhe Plates &amp; Bone Screws (Non-Locking)</li> <li>5. SOSPL, Sharma Otrtho and Sahrma/ Spinal Implants</li> <li>6. SOSPL, Sharma Otrtho and Sahrma/ Artho-Scopy Implant Pins &amp; Wires</li> <li>7. SOSPL, Sharma Otrtho and Sahrma/ Orthope Dic Implants (Prothesis &amp; Joints Replacements)</li> </ol>	Mfg Lic in Form 28 vide no. G/28/1432 ( valid form 19-02-2013 to 18-02-2018)
30.	M/s. Disposafe Health & Life Care Ltd., Plot No. 1 & 2, Sector- 59, Ballabgarh - 121004	<ol style="list-style-type: none"> <li>1. Dispoflon / Sterilized Intravenous Cannula</li> <li>2. Dispon/ Sterilized Intravenous Cannula</li> </ol>	Mfg Lic in Form 28 vide no. 714-B (H) ( valid 27-05-2013 up to 26-05-2018)



31.	M/s. Nano Therapeutics Private Limited, D-54/2 Hoziwala Industrial Estate, Sachin, Surat, Gujarat-394230	<ol style="list-style-type: none"> <li>1. Coreal Coronary Stent System/ Cobalt Chromium Coronary Stent System</li> <li>2. Ambeal Coronary Stent System/ Cobalt Chromium Coronary Stent System</li> <li>3. Sparkel Coronary Stent System/ Stainless Steel Coronary Stent System</li> <li>4. Endurex Coronary Stent System/ Stainless Steel Coronary Stent System</li> <li>5. Siromount Coronary Stent System/ Biodegradable Polymer Based Sirolimus Eluting Coronary Stent System Platform: Cobalt Chromium</li> <li>6. Cruzon Coronary Stent System/ Biodegradable Polymer Based Sirolimus Eluting Coronary Stent System Platform: Cobalt Chromium</li> <li>7. Siroflex Coronary Stent System/ Biodegradable Polymer Based Sirolimus Eluting Coronary Stent System Platform: Cobalt Chromium</li> <li>8. Encruso Coronary Stent System/ Biodegradable Polymer Based Sirolimus Eluting Coronary Stent System Platform: Cobalt Chromium</li> <li>9. Cornet Abettor Balloon Expandable Peripheral Stent System/ Balloon Expandable Cobalt Chromium Peripheral Stent System</li> <li>10. Cornet REsure Balloon Expandable Renal &amp; Biliary Stent System/ Balloon Expandable Cobalt Chromium Real 7 Biliary Stent System</li> <li>11. Expulsar Paclitaxel Drug Eluting Dilatation Balloon Catheter (PTCA &amp; PTA)/ Paclitaxel Drug Eluting Dilatation Balloon Catheter (PTCA &amp; PTA)</li> </ol>	Mfg Lic in Form 28 vide no. G/28/1395 ( valid up to 11-12-2016)
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