

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

#	Name of the Manufacturer	Product Licenced by CLAA	Manufacturing Licence No. & Validity
1.	M/s. Vascular Concepts (P) Ltd., No.345, 14 th Main Road, RMV Extension, Bangalore-80	<p><u>Cardiac Stents:</u></p> <ol style="list-style-type: none"> 1. Coronary Stent System [Prolink LP] 2. Coronary Stent [Prolink] 3. Platinum Activated Stent [Propass] 4. Platinum Activated Stent System [Propass] 5. Coronary Stent [Prolink SV] 6. Coronary Stent System [Prolink SV] 7. PTCA Catheters [Speed] <p><u>Drug Eluting Stents:</u></p> <ol style="list-style-type: none"> 1. Sirolimus Eluting Stent System [Pronova] 2. Sirolimus Eluting Stent System [Pronova XR] 3. Balloon Expandable Peripheral Stent [Prostar] 4. Double Lumen Balloon Dialation catheter-Accessories for Accur Balloon – Sty let, LA wire, Metal stretching Tube and Syringe [Accura Balloon Catheter] 5. Balloon expandable Covered Stent [Prograft] 6. Sirolimus + Cyclosporin Eluting Stent System [procomm] 	Mfg. Lic. in Form 28 vide No. KTK/28/359/2006 (Nov. 2006 to Nov. 2011)

2.	M/s Relisys Medical Devices Limited, Ibrahimpattam Mandal, Ranga Reddy Distric-501 510, Andhra Pradesh.	<p><u>Cardiac Stents:</u></p> <ol style="list-style-type: none"> 1. Cardiac Stents (ETO Sterilised) Legend [Bare Metal uncoated] 2. Cardiac Stents (ETO Sterilised) Legend Mini [Bare Metal uncoated, Precrimped on the balloon] 3. Cardiac Stents (ETO Sterilised) Legend V [Bare Metal uncoated, Precrimped on the balloon] 4. Cardiac Stents (ETO Sterilised) Cobal + C Mini [Cobalt chromium stent precrimped on the balloon] 5. Cardiac Stents (ETO Sterilised) Cobal + C [Cobalt chromium stent precrimped on the balloon] <p><u>Drug Eluting Stents:</u></p> <ol style="list-style-type: none"> 1. Drug Eluting Stent (ETO Sterilised) Release-T Mini [Paclitaxel Eluting Stents] 2. Drug Eluting Stent (ETO Sterilised) Release-T [Paclitaxel Eluting Stents] 3. Drug Eluting Stent (ETO Sterilised) Corel + C Mini [Paclitaxel loaded on a porous carbon coated Cobalt Chromium Stent precrimped on the balloon] 4. Drug Eluting Stent (ETO Sterilised) Corel + C Mini [Paclitaxel loaded on a porous carbon coated Cobalt Chromium Stent precrimped on the balloon] 5. I.V. Cannula for Guide Wire Vascular Access Needle [Reference 18G X 7Cms. 	Mfg. Lic. in Form 28 vide No. 19/RR/AP/2006/MD/G (Nov. 2006 to Nov. 2011)
3.	M/s Eastern Medikit Limited, 195-196, Phase 1, Udyog Vihar, Gurgaon	<ol style="list-style-type: none"> 1. I.V. Cannula with various sizes and brand names 2. Catheters of various sizes and brand names 	Mfg. Lic. in Form 28 vide No. 634-B(H) (May 2007 to May 2012)
4.	M/s Eastern Medikit Limited, 205, Phase 1, Udyog Vihar, Gurgaon	<ol style="list-style-type: none"> 1. I.V. Cannula with various sizes and brand names 2. Catheters of various sizes and brand names 	Mfg. Lic. in Form 28 vide No. 638-B(H) (Sept.2006 to Sept. 2011)
5.	M/s. Mediplus India Limited, 1262, MIE, Bahadurgarh, Haryana	<ol style="list-style-type: none"> 1. I.V. Cannula with Injectin Valve and Wings- of various sizes and different Brand Names 2. Catheters of various types 	Mfg. Lic. in Form 28 vide No. 646-B(H) (June 2007 – May 2012)

6.	M/s. Hindustan Syringes & Medical Devices Ltd, 174-177, Sector 25, Ballabgarh, India	I.V.Cannula of various sizes	Mfg. Lic. in Form 28 vide No. 636-B(H) (Oct 2006 to Oct 2011)
7.	Vitromed healthcare, A- 27, Bais Godam Industrial Estate, Jaipur, Rajasthan	1. I.V. Cannula with various sizes and brand names 2. Catheters of various sizes and brand names 3. Scalp Vein Sets	Mfg. Lic. in Form 28 vide No. RAJ-2346 (Feb 2007 to Feb 2012)
8.	M/s Polymedicure Limited, Plot No. 104-105, Sector-59, HSIDC Indl. Estate, Ballabhgarh	1. I.V. Cannula of various sizes 2. Catheters of various sizes	Mfg. Lic. in Form 28 vide No. 644-B(H) (March.2006 to March 2011)
9.	Polymedicure Limited, Plot No. 115, Sector-59, HSIDC Indl. Estate, Ballabhgarh	1. I.V. Cannula of various sizes 2. Catheters of various sizes	Mfg. Lic. in Form 28 vide No. 627-B(H) (Sept.2006 to SEPT. 2011)
10.	M/s B. Braun Medical (I) Pvt. Limited, PII, 1 st Avenue Mahindra World City, Kancheepuram	1. Right Heart Catheters (Brand Names- Corodyn P1/ Corodyn P2/ Corodyn TD/ Corodyn TD-1/ Corodyn A/ Eledyn EB 10) 2. Foley Balloon Catheters (Silicon Elestomer, Plastic Valve)	Mfg. Lic. in Form 28 vide No.TN00002338 (June 2007 to June 2012)
11.	M/s Freedom Ophthalmic Pv0. Ltd., No.31, Phase I, SIPCOT Industrial Complex, SIPCOT, Hosur -6351261	Intra Ocular Lenses of various sizes	Mfg. Lic. in Form 28 vide No. TN00002315 (April 2006 to April 2011)

12.	M/s Sahajanand Medical Technologies Pvt. Ltd., Plot No. 168/96/A, Dabhel Industrial Co operative Society, M.G. Udyog Nagar, Dabhel, Daman	<p>1. Cardiac Stents</p> <ol style="list-style-type: none"> Flex- The Millennium Coronary Stent Flex- The Millennium Coronary Stent System SFX 108 - The Millennium Coronary Stent SFX 108- The Millennium Coronary Stent System MatrixTM- The Millennium Coronary Stent System CoronnumTM – Cobalt Chromium Coronary Stent System <p>2. Drug Eluting Stents</p> <ol style="list-style-type: none"> Infinium ©- Paclitaxel Eluting Coronary Stent system Supralimus©- Sirolimus Eluting Coronary Stent System Infinium Core – Cobalt Chromium Paclitaxel Eluting Coronary Stent System Supralimus Core – Cobalt Chromium Sirolimus Eluting Coronary Stent System 	Mfg. Lic. in Form 28 vide No. DD/537 (May 2007 - May 2012)
13.	M/s Lakhani Medicare Pvt. Limited, Plot No. 136, Sector-24, Faridabad, Haryana	<ol style="list-style-type: none"> IV Cannula of various sizes and different brand names Catheters – Foley Balloon Catheters / Nelation Catheters / Suction Catheters / Female Catheters / Rectal Catheters / Thoracic Catheters 	Mfg. Lic. in Form 28 vide No. 654-B(H) (August 2007 to July 2012)
14.	M/s. Biomed Health Care Pvt. LTD, 30 DLF , Industrial Estate-1, Faridabad , Haryana	IV Cannula of various sizes and different Brand Names	Mfg. Lic. in Form 28 vide No. 65I-B(H) (July 2007 to July 2012)
15.	M/s Biomed Health Care Products Pvt. Limited, Plot No.62-65, Sec.6A, SIDCUL, Ranipur, Haridwar, Uttarakhand	IV Cannula of various sizes and different Brand Names	Mfg. Lic. in Form 28 vide No. UA/SC/P-2007 (Nov. 2007 to Nov. 2012)
16.	M/s Hersoria Health Care Pvt. Limited, 110-111, Phase 4, Udyog Vihar, Gurgaon, Haryana	IV Cannula of various Brand Names	Mfg. Lic. in Form 28 vide No. 637-B(H) (Sept. 2006 – Sept. 2011)

<p>17.</p>	<p>M/s John Fowler Ophthalmics Pvt. Ltd., A-5 MIDC, Chikalathana Aurangabad</p>	<p>Intra Ocular Lenses</p> <ol style="list-style-type: none"> a. John Fowler Rigid Lense – PMMA (Models in posterior chamber, models in anterior chamber, models in Plano Convex) b. John Fowler Foldable Lenses – HEMA (of various sizes) 	<p>Mfg. Lic. in Form 28 vide No. AD/055 (Nov.2007 – Nov. 2012) CANCELLED ON FEB. 2008 DUE TO CHANGE IN NAME OF THE FIRM AND NEW LICENCE WAS GRANTED IN APRIL 2008</p>
<p>18.</p>	<p>M/s Biosync Scientific Pvt. Ltd., 136B, SEZ, Diamond Park, G.I.D.C., Sachin, Surat – 394230</p>	<p>BARE METAL STENT</p> <ol style="list-style-type: none"> a. GENX Coronary Stent & Stent System (Stainless Steel 316L) b. GENXCRCO Coronary Stent & Stent System (Cobalt Chromium L605) <p>ADDITIONAL PRODUCTS</p> <ol style="list-style-type: none"> a. Protea Coronary Stent and Stent System (Cobalt Chromium Coronary Stent System) b. Lotus Coronary Stent and Stent System (Stainless Steel Coronary Stent System) <p>FOR EXPORT ONLY</p> <ol style="list-style-type: none"> c. VestCOR Coronary Stent and Stent System (HAp coating on L605 Platform) d. VestaSync Coronary Stent and Stent System (Polymer free HAp coated Sirolimus Eluting Coronary Stent System) e. GenXSync Coronary Stent and Stent System (Biodegradable Polymer based Sirolimus Eluting Coronary Stent System) 	<p>Mfg. Lic. in Form 28 vide No. G/28/1261 (Oct 2007 – Oct 2012)</p>
<p>19.</p>	<p>M/s SISCO Latex Private Limited , No.35, Gopalan Kadai Road, Kurumbapet Village, Villianur Commune, Puducherry 605 009</p>	<p>Latex Foley Catheters</p> <ol style="list-style-type: none"> a. Two way Paediatric Foley Catheters, b. Two way Paediatric Foley Catheters- Female Catheters, c. Three way Foley Catheters, Silicone Elastomer coated Catheters d. Uterine Balloon Therapy Catheters, e. Special Tipped Catheters and f. All Silicone Catheters 	<p>Mfg. Lic. in Form 28 vide No. 07 22 2135 (Dec. 2007 to Dec. 2012)</p>

20.	M/s Lars Medicare Pvt. Ltd. Killa No.16, 17 Sultanpur G.T.Road, Bahalgarh, Distt. Sonepat.	I.V. Cannula of various sizes and different Brand Names	Mfg. Lic. in Form 28 vide No. 660-B(H) (Jan 2008 – Jan.2013)
21.	M/s Suru International Pvt. Ltd., Plot 5, Patilpada, Saravali, Jawar Road, Thane, Dahanu, Thane	1. I.V. cannula of various sizes and different Brand Names 2. Catheters of various types & different brand names	Mfg. Lic. in Form 28 vide No.KD-459 (Dec.2007 – Dec. 2012)
22.	M/s T.T.K. Health Care Ltd., KINFRA Park, Thumba, Thiruvananthapuram	1. Heart Valves (Aortic Valves and Mitral Valves in different sizes) 2. Polyester fabric for intra cardiac repair in different size	Mfg. Lic. in Form 28 vide No. 18/28/2007 (Dec.2007 – Dec.2012)
23.	M/s. Romsons Scientific & Surgical Industries Pvt. Ltd., 63, Industrial Estate, Nunhai, Agra, UP	1. Scalp Vein Sets 2. I.V. Cannula 3. Catheters	Mfg. Lic. in Form 28 vide No. 1/MD/2008 (Feb 2008 – Feb 2012)
24.	M/s. Hi-tech Medicare Devices Pvt.Ltd, H-16/1, UPSIDC, Industrial Area, Naini, Allahabad	IV Cannula	Mfg. Lic. in Form 28 vide No. 05/SC/PO/2008 (March 2008 to March 2013)
25.	M/s B.L.Life Sciences Pvt. Ltd., D-31, Site-IV, Kasana, Surajpur Greater Noida (UP)	1. Thoracic Drainage Catheter 2. Central Venous Catheters	Mfg. Lic. in Form 28 vide No. 03/SC/PO/2008 (Feb.2008 – Feb.2013)
26	M/s Basic Healthcare Products Pvt. Ltd., Plot No.1- F E.P.I.P. Phase-I, Jharmanri Baddi, Tehsil Nalagarh, Distt. Solan, H.P..	1. Hydroxyapatite Ceramic Surgical Implant Products (B-OstIN) 2. Metal Surgical Implant Products (B-Saf)	Mfg. Lic. in Form 28 vide No. MB/08/682 (APRIL 2008 – APRIL 2013)

27.	M/s Sterimed Medical Devices (P) Ltd., 38 KM. Stone, Delhi Rohtak Highway, Bahadurgarh, Haryana	<ol style="list-style-type: none"> 1. I.V.Cannula 2. Catheters 	
28.	M/s. Adler Mediequip Pvt. Ltd, At – Muradpur, PO Hatim, Taluk Sangmeshwar, Ratnagiri, Maharashtra 415.	Orthopedic implants (Brand Names : Adler, Sushrut, UMEX, Eazee, Zeta, Onelock, Titan, Endofix, Atlas, ResTOR, Accis, Axilock, CerviEdge, CerviTwin, Moduloc, Adler Legend, Adler Endofit, Atlas Proxima)	Mfg. Lic. in Form 28 vide No. KD-469 (May 2008 – May 2013)
29.	M/s John Fowler Ocular Lenses Pvt. Ltd., A-5 MIDC, Chikalhana Aurangabad	<p>Intra Ocular Lenses</p> <ol style="list-style-type: none"> a. John Fowler Rigid Lense – PMMA (Models in posterior chamber, models in anterior chamber, models in Plano Convex) b. John Fowler Foldable Lenses – HEMA (of various sizes) 	NEW LICENCE Mfg. Lic. in Form 28 vide No. AD/058 (April 2008 – April 2013)
30.	M/s Meril Life Sciences Pvt. Ltd., Near G. M. Bilakhia Stadium, Muktanand Marg, Chala, Vapi-396191	<p>Cardiac Bare Metal Stents</p> <ol style="list-style-type: none"> a. Crypton™ Coronary Stent & Stent System (Stainless Steel) b. NexGen™ Coronary Stent & Stent System (Cobalt Chromium) c. Osum™ Coronary Stent & Stent System (Cobalt Chromium) 	Mfg. Lic. in Form 28 vide No. G/28/1273 (June 2008 – June 2013)
31.	M/s. Surgimedik Healthcare India Pvt Ltd, 53, CD Kandivali Industrial Estate, Kandivali (West), Charkop, Mumbai.	<ol style="list-style-type: none"> 1. Surgimedik Urological Catheters 2. Surgimedik Gynaecological Catheters 3. Surgimedik Gastroenterological Catheters 4. Surgimedik Nephrological Catheters 5. Surgimedik Radiological Catheters 6. Surgimedik Oncological Catheters 	Mfg. Lic. in Form 28 vide No. MH004562 (April 2007 – April 2012)