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

(Jan. 2011 to August 2011)

<table>
<thead>
<tr>
<th>#</th>
<th>Name of the Manufacturer</th>
<th>Product Licenced by CLAA</th>
<th>Manufacturing Licence No. &amp; Validity</th>
</tr>
</thead>
</table>
| 1. | M/s. Suretech Medical Inc., 333, Khurana Compound, I.B. Patel Road, Goregaon (East), Mumbai- 400063 | 1. Product Group: Catheters  
a. PCN Catheter  
b. PCN Catheter with needle  
c. Dialysis Catheter  
d. Uretric Catheter  
e. Double J Stent  
f. Suction Catheter  
2. Products Group: Needle  
a. Introducer Needle  
b. Aspiration Needle  
c. Biopsy Needle/ Core Biopsy Needle/ Giopsy Gun- Auto/ Semi Automatic  
d. Chiba Needle  
e. Breast Localisation Needle  
f. Fistula Needle  
3. Angio Kit  
4. 3 Way stop cock with extension  
5. Guide wire  
<table>
<thead>
<tr>
<th></th>
<th>Company Name</th>
<th>Medical Devices</th>
<th>Mfg Lic in Form 28 vide no.</th>
</tr>
</thead>
</table>
2. Catheter Sterile Disposable Single Use Urethral Catheters Size: [FG4/6/8/10/12/14/16/18/20] “ALPHA” Brand Sterile Disposable Single Use Urethral Catheters  
3. Catheter Sterile Disposable Single Use Nalaton Catheters Size: [FG4/6/8/10/12/14/16/18/20] “ALPHA” Brand Sterile Disposable Single Use Nalaton Catheters  
8. Catheter Sterile Disposable Single Use Nasal Gastric Tube Catheters Size: [FG4/6/8/10/12/14/16/18/20] “ALPHA” Brand Sterile Disposable Single Use Nasal Gastric Tube Catheters | G/28/1359 (07/12/2010 to 06/12/2015) |
| 3. | M/s Mediplus (India) Ltd., 1261-1262 MIE Bahadurgarh Haryana 124507 | 1. Vivon Cath (tkl)  
2. Vivon  
3. Canusoft | 646 B (H) Valid up to 31/05/2012 |
1. I.V. Cannula (Intravenous Cannula) “ANGEL TOUCH” Brand  
2. Catheter Sterile Disposable Single use Ryle’s Tube  
3. Catheter Sterile Disposable Single use Stomach Tube  
4. Catheter Sterile Disposable Single use Levin’s Tube  
5. Catheter Sterile Disposable Single use infant Feeding Tube  
6. Catheter Sterile Disposable Single use infant Mucus Extractor  
7. Sterile Disposable Single use Karman Cannula with & Without adaptor  
8. Sterile Disposable Single use Endotracheal Tube With & Without Cuff  
9. Catheter Sterile Disposable Single use Tracheotomy Tube With & Without Cuff  
10. Sterile Disposable Single use Scalp Vein Set  
11. Catheter Sterile Disposable Single use Close Wound Suction Unit  
12. Catheter Sterile Disposable Single use Nelaton Catheter  
13. Catheter Sterile Disposable Single use Nasal Oxygen Catheter  
14. Catheter Sterile Disposable Single use Suction Catheter  
15. Catheter Sterile Disposable Single use Rectal Catheter  
16. Catheter Sterile Disposable Single use Urethral Catheter  
17. Catheter Sterile Disposable Single use Umbilical Catheter  
18. Catheter Sterile Disposable Single use Foley Balloon Catheter  
19. Catheter Sterile Disposable Single use Thoracic Catheter with trocar  
20. Catheter Sterile Disposable Single use Male External Catheter  
21. Sterile Disposable Single use Haemodialysis Tubing Set/Blood Tubing Set/Arterial Venous Tubing Set  
22. Catheter Sterile Disposable Single use Thoracic Catheter  
| 5. | M/s Becton Dickinson India Pvt. Ltd., Plot # 1, Sector-3, Industrial Growth Center, Bawal, Distt. Rewari, Haryana | For sale or distribution into domestic Market and Export Purpose  
1. Sterile, Single-Use Intravascular Catheter Gauge 14  
2. Sterile, Single-Use Intravascular Catheter Gauge 14 | Mfg Lic in Form 28 vide no. 671-B(H) (24/03/2009 to 23/03/2014) |
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>6.</td>
<td>M/s Poly Medicure Ltd., Plot No. 17, Sector-3, I.I.E, Sidcul,, Ranipur Haridwar, 249403, Uttarakhand</td>
<td></td>
<td>1. Sterile I.V. Cannula for Single use only (Brand - POLYFLON) 2. Sterile I.V. Cannula for Single use only (Brand - POLYFLON) 3. Sterile I.V. Cannula for Single use only (Brand - POLYFLON) 4. Sterile I.V. Cannula for Single use only (Brand - POLYFLON) 5. Sterile I.V. Cannula for Single use only (Brand - POLYFLON) 6. Sterile I.V. Cannula for Single use only (Brand - POLYFLON) 7. Sterile I.V. Cannula for Single use only (Brand - POLYFLON) 8. Sterile I.V. Cannula for Single use only (Brand - POLYFLON) 9. Sterile I.V. Cannula with Luer Lock &amp; Injection Port Radiopaque for single use only (ULTRA) 10. Sterile I.V. Cannula with Luer Lock &amp; Injection Port Radiopaque for single use only (ULTRA) 11. Sterile I.V. Cannula with Luer Lock &amp; Injection Port Radiopaque for single use only (ULTRA) 12. Sterile I.V. Cannula with Luer Lock &amp; Injection Port Radiopaque for single use only (ULTRA) 13. Sterile I.V. Cannula with Luer Lock &amp; Injection Port Radiopaque for single use only (ULTRA) 14. Sterile I.V. Cannula with Luer Lock &amp; Injection Port Radiopaque for single use only (ULTRA) 15. Sterile I.V. Cannula with Luer Lock &amp; Injection Port Radiopaque for single use only (ULTRA) 16. Sterile I.V. Cannula with Luer Lock &amp; Injection Port Radiopaque for single use only (ULTRA)</td>
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Mfg Lic in Form 28 vide no. 51/UA/SC/P-2009 Valid upto 18/06/2014

G/28/1352 (27/09/2010 to 26/09/2015)
| **8.** | M/s Biotech Vision Care Pvt. Ltd., 555-557, Opposite Subham Tel-O-Pack, Khatrajvadsar Road, AT & Post Khatraj, Tal. Kalol, Distt. Gandhinagar- 382729 | FOR DOMESTIC USE ONLY  
1. PMMA INTRA OCULAR LENSES (NON - FOLDABLE CATEGORY) - BIOVISION  
2. PMMA SURFACE MODIFIED INTRA OCULAR LENS (NON - FOLDABLE) - NUCLEUS  
3. HYDROPHILIC ACRYLIC FOLDABLE INTRA OCULAR LENSES - EYECRYL  
4. HYDROPHILI ACRYLIC FOLDABLE INTRA OCULAR LENS- EYECRYL PLUS  
5. HYDROPHILI ACRYLIC FOLDABLE INTRA OCULAR LENS- EYECRYL PLUS HYDROPHOBIC SURFACE  
6. HYDROPHILI INTRA OCULAR LENSES- (FOLDABLE CATEGORY) - EYECRYL PLUS HYDROPHOBIC | Mfg Lic in Form 28 vide no. G/1298 (27/09/2010 to 26/09/2015) |
| **9.** | M/s Global Medikit Ltd., Khasra no. 323 (MI), Camp Road, Selequi, Dehradun, Uttrakhand | 1. Gloflon Safety 1  
2. Gloflon Safety 2  
3. Corona  
4. Medicent  
5. Centurm Uno  
6. Centrum Duo  
7. Centrum Trio  
8. Epidural Mini Pack | Mfg Lic in Form 28 vide no. 18/UA/SC/P-2009 Valid up to 23/03/2014) |
2. Bone Plates (Non sterile)  
3. IM Nails (Non sterile)  
4. Spine Implants (Non Sterile)  
5. Corvical Implants (Non Sterile) | Mfg Lic in Form 28 vide no. G/28/1301 valid up to 27/04/2014) |
<p>| <strong>12.</strong> | M/s Lars Medicare Pvt. Ltd., Kila no. 16 &amp; 17, Sultanpur, G.T. road, Bahalgarh, Sonepat Haryana | 1. I.V. Cannula with injection valve | Mfg Lic in Form 28 vide no. 660-B-H Valid up to 03/02/2013) |</p>
<table>
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</table>
| 13  | M/s Shree Umiya Surgical Pvt. Ltd., Plot No. 4704, Phase IV, G.I.D.C., Vatva, Ahmedabad- 382445 | 1. Transfusion  
2. Gastroenterology  
3. Gastroenterology  
4. Gastroenterology  
5. Gastroenterology  
6. Gastroenterology  
7. Gastroenterology  
8. Pediatric  
9. Gynecology  
10. Anaesthesia  
11. Anaesthesia  
12. Infusion & Transfusion  
13. Surgery  
14. Surgery  
Catheters:  
15. Urology  
16. Anaesthesia  
17. Anaesthesia  
18. Anaesthesia  
19. Anaesthesia  
20. Miscellaneous  
21. Urology  
22. Surgery  
23. Urology  
24. Haemodialysis Catheter  
25. Anaesthesia | Mfg Lic in Form 28 vide no. G/28/1329 (19/03/2010 to 18/03/2015) |
| 14  | M/s. Multi Medics, Plot No. 28, HPSIDC, Phase-III, baddi, Distt-Solan (H.P.)-17205 | 1. M’Sure  
2. M’Sure-Cr  
3. M’Sure-S | Mfg Lic in Form 28 vide no. MB/10/836 (22/01/2011 to 21/01/2016) |
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<td>15.</td>
<td>M/s. Airways Surgicals Private Limited, Plot No. 2209 &amp; 2210 Phase-IV, G.I.D.C., Vatva, Ahmedabad</td>
<td>- Hemodialysis Catheter&lt;br&gt;- Suction Catheter&lt;br&gt;- Thoracic Catheter with Trocar&lt;br&gt;- Epidural Catheter with or without Needle size&lt;br&gt;- Urethral catheter&lt;br&gt;- Foley’s Catheter&lt;br&gt;- Central line Catheter&lt;br&gt;- Swivel Mount Catheter&lt;br&gt;- Endotracheal &amp; Re-Inforce Endotracheal Tube with &amp; without Cuff&lt;br&gt;- Aero Care Close Suction System&lt;br&gt;- Tracheotomy Tube with &amp; without Cuff&lt;br&gt;- Aero Vac Set&lt;br&gt;- Angioplasty Kit&lt;br&gt;- Aero Pressure Monitoring Line&lt;br&gt;- Three Way stop cock&lt;br&gt;- Three way Extension Line&lt;br&gt;- Ryle’s Tube Size&lt;br&gt;- Infant Feeding Tube&lt;br&gt;- Scalp Vain Set&lt;br&gt;- Laryngal Mask Airway&lt;br&gt;- Pressure Transducer Catheter</td>
<td>Mfg Lic in Form 28 vide no. G/28/1362 (10/01/2011 to 09/01/2016)</td>
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<tr>
<td>17.</td>
<td>M/s. Uma Surgicals, Gala No. 21/22, Gayatri Industrial Estate, Village-Navghar, Tal-Vasai, Distt-Thane (Maharashtra)</td>
<td>- Bone Screw&lt;br&gt;- Bone Plate&lt;br&gt;- Intra Medullary Nail&lt;br&gt;- Pins and Wires&lt;br&gt;- Spinal Implants</td>
<td>Mfg Lic in Form 28 vide no. KD-491 (09/06/2010 to 08/06/2015)</td>
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<td>No.</td>
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<td>Products</td>
<td>Manufacturing License Details</td>
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| 18. | M/s. Uma Surgicals, Gala No. 21/22, Gayatri Industrial Estate, Village-Navghar, Tal-Vasai, Distt-Thane (Maharashtra) | 1. Bone Screw  
2. Bone Plate  
3. Intra Medullary Nail  
4. Pins and Wires  
5. Spinal Implants | Mfg Lic in Form 28 vide no. KD-490 (09/06/2010 to 08/06/2015) |
2. Bone Screws  
3. Intramedullary Nails  
4. Wire, Pin & Washer  
5. Other Implants  
6. Spinal Implants  
7. Joint Replacement Prosthesis  
8. External Fixation System | Mfg Lic in Form 28 vide no. G/28/1365 (24/02/2011 to 23/02/2016) |
2. Biliary Duct Drainage Catheter  
3. Percutaneous Pigtail Nephrostomy Catheter  
4. External Biliary Drainage Catheter  
5. IUI Catheters  
6. Percutaneous malecot Nephrostomy catheter  
7. Naso Biliary Drainage catheter  
8. Nephrostomy catheter  
9. Percutaneous Biliary Drainage Catheter  
10. Plural Drainage Catheter  
11. Suprapubic Cystostomy Catheter  
12. Tieman Catheter  
13. Percutaneous Pigtail Suprapubic Catheter  
14. Ureteral Catheter  
15. Urinary Catheters | Mfg Lic in Form 28 vide no. KTK/28/395/2009 (06/06/2011 to 15/06/2016) |
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