| | | FI | LE I | No. DCEO/GeM/AVM/ | | Dra | aft 1 1 | 2.10.2018 | | | | | | |
|-----------|---|------------------|------|--|---------------|----------|------------|------------|------------|------------|----------------|---------------------------------------|-----------------------------|------------------|
| | Creator: Mr. Ajmer Singh(TA |) N | Iode | erator : Shri A.V.Muralidhara | n (Dy. C | CEO GeM | I) Ap | prover :S | hri A F | K Kamr | a (Ad. C | EO GeN | (1) | |
| | Ma | ijor ca | ateg | ory:Patient exam and monito | ring prod | lucts | -UNSF | PSC - 4218 | 0000 | | | | | |
| | | Su | b C | ategory :Ophthalmic diagnost | ic exam p | oroducts | - UNSI | PSC Code | - 4218 | 3000 | | | | |
| | | | | Hand held kerotomete | er : UNSI | PSC Code | - 4218 | 83035 | | | | | | |
| S.N o. | Parameters | Gro upin g | | Value 1 | Value2 | Value 3 | Value 4 | Value 5 | Value 6 | Golde n | Validatio n | Wheth er Filter Requir ed | p r i i t o y r | U n i t |
| 1 | Purpose | P | E | A keratometer or an ophthalmometer is a diagnostic instrument for measuring the curvature of the anterior surface of the cornea, particularly for assessing the extent and axis of astigmatism | | | | | | G | | | | |
| 2 | Range of corneal curvature radius in mm | D | Е | 5 to 10 | 5.5 to 12 | | | | | G | | | | mm |
| 3 | Step in adjustment to attain corneal curvature radius in mm | D | Е | 0.01 | 0.05 | | | | | G | | | | mm |
| 4 | Range of refractive power/Refraction in diopter | D | Е | 33.75 to 67.50 | 28 to 60 | | | | | G | | | | D |
| 5 | Refraction index (n) | D | N | 1.3375 | | | | | | G | | | | |
| 6 | Step to attain refractive power in diopter | D | Е | 0.01 | 0.12 | 0.25 | | | | G | | | | D |
| 7 | Range of Astigmatism in diopter | D | Е | 0 to -10 | 0 to +10 | | | | | G | | | | D |
| 8 | Step to attain Astigmatism in diopter | D | Е | 0.01 | 0.12 | 0.25 | | | | G | | | | D |
| 9 | Range of axis angle in degree | D | Е | 0 to 180 | | | | | | G | | | | degree |
| 10 | Step to attain axis angle in degree | D | Е | 1 | | | | | | G | | | | degree |
| 11 | Measuring area in mm | D | Е | 3.3 | | | | | | G | | | | mm |
| 12 | Range ofrefractive power for Eccentricity in diopter | D | Е | 4.10 to -2.05 | 4.10 to +2.05 | | | | | G | | | | |
| 13 | Quality of measuring angle | P | Е | Superior | Inferior | | | | | G | | | | |

| 14 | Measuring angle should be temporal | P | Е | Yes | | | | | G | | |
|----|--|-----|----------|---------------------------|-----------------|-------------------------------------|---|---|---|--|--------|
| | Magnification for eyepiece | D | Е | 15 x | | | | | G | | |
| 16 | Availabilty of dual eye level sighting system | P | Е | Yes | | | | | G | | |
| 17 | Availability of chin rest | P | Е | Yes | | | | | G | | |
| 18 | Nasal angle from centre in degree | D | Е | 25 | | | | | G | | degree |
| 19 | Measuring time in sec | D | Е | 0.1 | | | | | G | | sec |
| 20 | Magnification for observation window | D | Е | 2x | | | | | G | | |
| 21 | Size of observation window (W x H) in mm x mm | D | Е | 54 x 16 | | | | | G | | mm |
| 22 | l Motorised table should be supplied | P | Е | Yes | | | | | G | | |
| 23 | Power supply | P | Е | Single phase 230 V, 50 Hz | | | | | | | |
| 24 | Keratometer should have well illuminated circular mires with + sign | P | Е | Yes | | | | | G | | |
| 25 | Size of Keratometer (L xW xH) in mm x mm x mm | D | Т | | | | | | | | mm |
| 26 | Weight of Keratometer in kg | D | N | | | | | | | | kg |
| 27 | No.of spare bulb provided | P | Е | 1 | 2 | 3 | 4 | 5 | G | | |
| 28 | Hand Held Keratometer must be rust proof & proctective dust cover should be supplies with it. | P | Е | Yes | | | | | G | | |
| 29 | Productr should be made up of high quality material, pretreated with materials providing good finish, scratch resistant, bacteriostatic coating. | P | Е | Yes | | | | | | | |
| 30 | | P | Е | | | | | | | | |
| 31 | Product instruction manual shall be supplied in 3 sets | P | Е | Yes | | | | | | | |
| 32 | | | | | | | | | | | |
| 33 | Certifications for product | C&R | Е | US FDA | Europe an CE | Both US FDA & Europea n CE | | | | | |
| 34 | Certification No. and date to be indicated | C&R | Te xt | | | | | | | | |

| 35 | certification for quality standards | C&R | | Yes | No | | | | | | | | | |
|----|---|-----|----------|-----|---------------------------------------|--|--|--|--|--|--|--|--|--|
| 36 | ISO certification No and Date.If no ISO certification availbale put NA | C&R | Te xt | | | | | | | | | | | |
| 37 | Copies of reports and certifications to be furnished to buyer on demand at time of supplies | C&R | Е | Yes | NA | | | | | | | | | |
| | | | | | | | | | | | | | | |
| | Mr. Ajmer Singh(TA) | | | | Shri A.V.Muralidharan (Dy. CEO GeM) | | | | | | | | | |