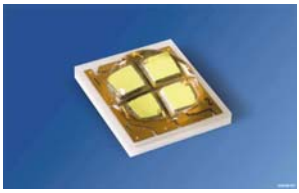
OSRAM OSTAR - Lighting plus
无铅设计，符合 RoHS
Lead (Pb) Free Product - RoHS Compliant

LE UW S2LN



初步数据 / Preliminary data

特点
- **封装：**紧凑型光源，贴片多芯片技术，备硅树脂透镜
- **装置特点：**完美表面发射，高密度芯片封装，亮度出色，照度卓越
- **典型光通量：**425 lm（工作电流为 350 mA 时）
- **典型色温：**6500 K
- **典型显色指数：**70
- **全视角：**140°
- **焊接方式：**回流焊接
- **ESD 耐压：**可达 2 kV（符合 JESD22-A114-D 标准）
- **出众的耐腐蚀性：**详细说明请参见第 13 页
- **耐潮湿性：**详细说明请参见第 13 页

Features
- **Package:** compact light source in multi chip SMT technology with silicone lens
- **Feature of the device:** outstanding brightness and luminance due to pure surface emission and high chip packing density
- **Typical Luminous Flux:** 425 lm at 350 mA
- **Typ. color temperature:** 6500 K
- **Typ. color rendering index:** 70
- **Viewing angle:** 140°
- **Soldering methods:** reflow soldering
- **ESD-withstand voltage:** up to 2 kV acc. to JESD22-A114-D
- **Superior Corrosion Robustness:** details see page 13
- **Humidity Robustness:** details see page 13

应用
- 商店照明
- 聚光灯和工作灯
- 改装灯取代型灯泡及灯具
- 反光灯应用
- 筒灯

Applications
- Shop lighting
- Spot- and tasklights
- Retrofit lamps
- Applications using reflector lamps
- Downlights

订购信息
Ordering Information

类型 Type	色温 Color temperature	光通量 第20页 1) Luminous Flux[1) page 20] I_F = 350 mA Φ_V (lm)	光通量 第20页 1) Luminous Flux[1) page 20] I_F = 350 mA Φ_V (lm)	订购代码 Ordering Code
LE UW S2LN-NYPX-5C8E	6500K	330... 520	425（典型值）/(typ.)	Q65110A9750
LE UW S2LN-NYPX-5E8G	6000K	330... 520	425（典型值）/(typ.)	Q65110A9751

注释： 上述类型编号代表仅包含几个亮度组的订购组（详细说明请参见**第 7 页**）。每个卷盘上仅装运一个亮度组（一个卷盘上不会混装两个亮度组）。例如，LE UW S2LN-NYPX-5C8E 表示任何一个卷盘上仅可装运一个亮度组：NY、NZ 或 PX。
为了确保可用性，单个亮度组将不接受订购。

类似地，对于需要测量和分选色度坐标组的颜色，每个卷盘上将仅装运单个色度坐标组。例如，LE UW S2LN-NYPX-5C8E 表示仅可装运从 5C 到 8E 范围内的一个色度坐标组（详细说明请参见**第 5 页**）。
为了确保可用性，单个色度坐标组将不接受订购。

Note: The above Type Numbers represent the order groups which include only a few brightness groups (see **page 7** for explanation). Only one group will be shipped on each reel (there will be no mixing of two groups on each reel). e.g. LE UW S2LN-NYPX-5C8E means that only one group -NY, -NZ or -PX will be shippable for any one reel.
In order to ensure availability, single brightness groups will not be orderable.

In a similar manner for colors where chromaticity coordinate groups are measured and binned, single chromaticity coordinate groups will be shipped in any one reel. e.g. LE UW S2LN-NYPX-5C8E means that only 1 chromaticity coordinate group -5C to -8E will be shippable (see **page 5** for explanation).
In order to ensure availability, single chromaticity coordinate groups will not be orderable.

最大额定值
Maximum Ratings

参数 Parameter	符号 Symbol	值 Values	单位 Unit
工作温度范围* Operating temperature range*	T_{op}	– 40 … + 110	°C
储存温度范围 Storage temperature range	T_{stg}	– 40 … + 110	°C
结点温度 Junction temperature	T_j	110	°C
正向电流（直流）/芯片 （最小值）/ (min.) Forward current per chip DC （最大值）/ (max.) (T_S = 25°C)	I_F	100 700	mA mA
浪涌电流 Surge current ≤ 10 µs, D = 0.1, T_S = 25°C	I_{FM}	2000	mA
反向电压 Reverse voltage (T_S = 25°C)	V_R	並非为反向运行而设计 not designed for reverse operation	V

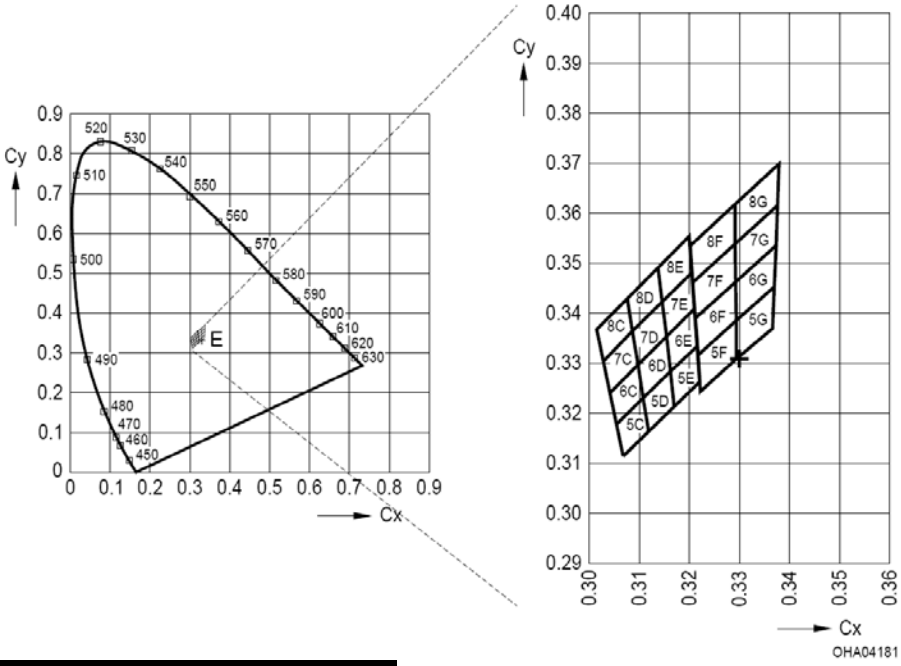
特性
Characteristics
(T_S = 25°C)

参数 Parameter	符号 Symbol	值 Values	单位 Unit
CIE 1931 色度坐标 x 第20页 3)（典型值）/ (typ.) Chromaticity coordinate x acc. to CIE 1931[3) page 20] I_F = 350 mA	x	0.31	–
CIE 1931 色度坐标 y 第20页 3)（典型值）/ (typ.) Chromaticity coordinate y acc. to CIE 1931[3) page 20] I_F = 350 mA	y	0.32	–
50 % I_V 时的全视角（典型值）/ (typ.) Viewing angle at 50 % I_V	2φ	140	度 deg.
正向电压/芯片 第20页 4)（最小值）/ (min.) Forward voltage per chip[4) page 20]（典型值）/ (typ.) I_F = 350 mA（最大值）/(max.)	V_F V_F V_F	2.7 3.2 3.7	V V V
反向电流（最大值）/(max.) Reverse current (U_R = 0.5V)	I_R	并非为反向运行而设计 not designed for reverse operation	µA
光效（典型值）/ (typ.) Optical efficacy I_F = 350 mA	η_V	100	lm/W
辐射面（典型值）/ (typ.) Radiating Surface	A	2.4 x 2.4	mm²
热阻 Thermal resistance			
结点/焊点（典型值）/ (typ.) Junction/solder point（最大值）/(max.)	$R_{th\ JS\ real}$ $R_{th\ JS\ real}$	4.2 5.0**	K/W K/W
$R_{th\ eff}$（20% 光效时）/ $R_{th\ eff}$ with 20% eff.			K/W
结点/焊点（典型值）/ (typ.) Junction/solder point（最大值）/(max.)	$R_{th\ JS\ eff}$ $R_{th\ JS\ eff}$	3.5 4.2**	K/W K/W

* 第 5 页的单个组
Individual groups on page 5

** $R_{th\ (最大值)}$ 取自统计值
$R_{th(max)}$ is based on statistic values

色度坐标组 第20页 3)
Chromaticity coordinate groups3) page 20



组 Group	Cx	Cy
5C	0.3068	0.3113
	0.3055	0.3177
	0.3108	0.3229
	0.3119	0.3162
6C	0.3055	0.3177
	0.3041	0.3240
	0.3098	0.3296
	0.3108	0.3229
7C	0.3041	0.3240
	0.3028	0.3304
	0.3087	0.3363
	0.3098	0.3296
8C	0.3028	0.3304
	0.3015	0.3368
	0.3076	0.3430
	0.3087	0.3363

组 Group	Cx	Cy
7E	0.3154	0.3352
	0.3146	0.3422
	0.3205	0.3481
	0.3210	0.3408
8E	0.3146	0.3422
	0.3138	0.3492
	0.3200	0.3554
	0.3205	0.3481
5F	0.3222	0.3243
	0.3217	0.3316
	0.3293	0.3384
	0.3294	0.3306
6F	0.3217	0.3316
	0.3212	0.3389
	0.3292	0.3461
	0.3293	0.3384

组 Group	Cx	Cy
5D	0.3119	0.3162
	0.3108	0.3229
	0.3162	0.3282
	0.3170	0.3212
6D	0.3108	0.3229
	0.3098	0.3296
	0.3154	0.3352
	0.3162	0.3282
7D	0.3098	0.3296
	0.3087	0.3363
	0.3146	0.3422
	0.3154	0.3352
8D	0.3087	0.3363
	0.3076	0.3430
	0.3138	0.3492
	0.3146	0.3422
5E	0.3170	0.3212
	0.3162	0.3282
	0.3216	0.3334
	0.3221	0.3261
6E	0.3162	0.3282
	0.3154	0.3352
	0.3210	0.3408
	0.3216	0.3334

组 Group	Cx	Cy
7F	0.3212	0.3389
	0.3207	0.3462
	0.3291	0.3539
	0.3292	0.3461
8F	0.3207	0.3462
	0.3202	0.3535
	0.3291	0.3617
	0.3291	0.3539
5G	0.3294	0.3306
	0.3293	0.3384
	0.3369	0.3451
	0.3366	0.3369
6G	0.3293	0.3384
	0.3292	0.3461
	0.3373	0.3534
	0.3369	0.3451
7G	0.3292	0.3461
	0.3291	0.3539
	0.3376	0.3616
	0.3373	0.3534
8G	0.3291	0.3539
	0.3291	0.3617
	0.3379	0.3698
	0.3376	0.3616

亮度组
Brightness Groups

亮度组 Brightness Group	光通量 第20页 2) Luminous Flux[2] page 20 Φ_V (lm)
NY	330 ... 390
NZ	390 ... 450
PX	450 ... 520

注释： 系列类型的标准装运格式包括仅由几个单个亮度组组成的产品族亮度组。单个亮度组不接受订购。

Note: The standard shipping format for serial types includes a family group of only a few individual brightness groups. Individual brightness groups cannot be ordered.

标签上的组名
Group Name on Label

示例：NX-5C

Example: NX-5C

亮度组 Brightness Group	色度坐标组 Chromaticity coordinate group
NX	5C

注释： 每个包装单元均仅包含一个组。

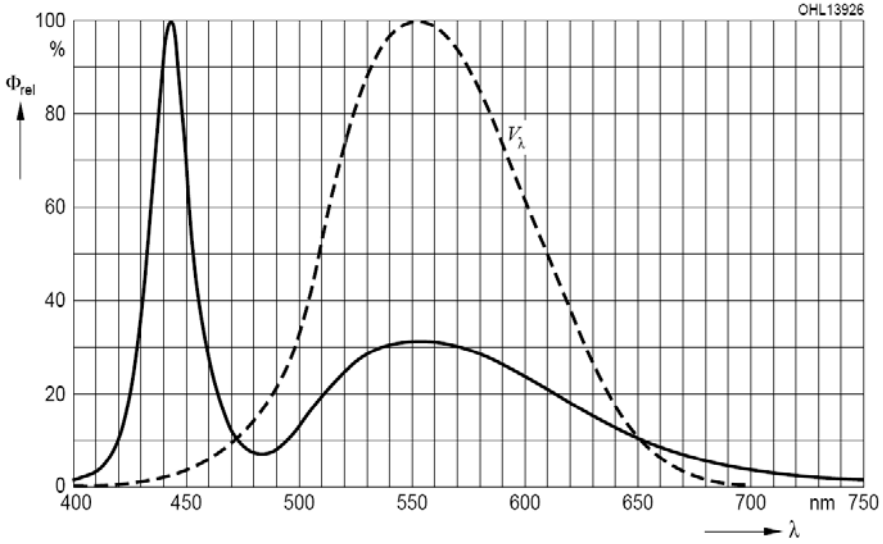
Note: No packing unit ever contains more than one group for each selection.

相对幅射光谱 第20页 2)

Relative spectral Emission2) page 20

V(λ) = 标准视觉曲线 / Standard eye response curve

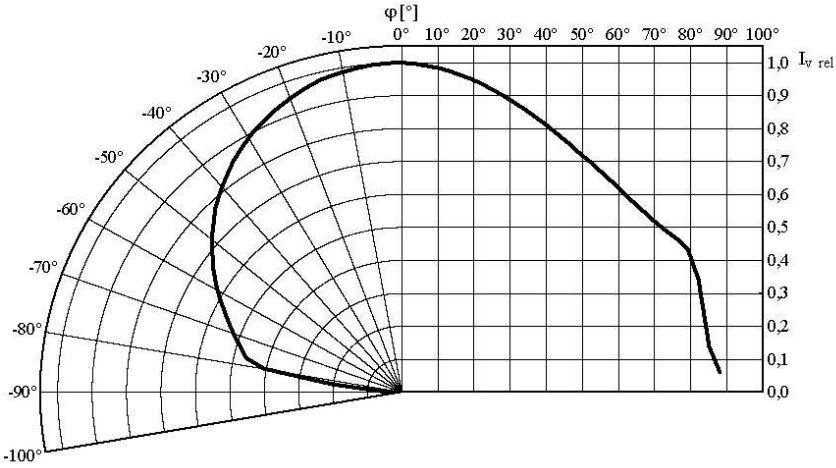
$\Phi_{rel} = f(\lambda)$, $T_S = 25°C$, $I_F = 350$ mA



配光曲线 第20页 2)

Radiation Characteristic 2) page 20

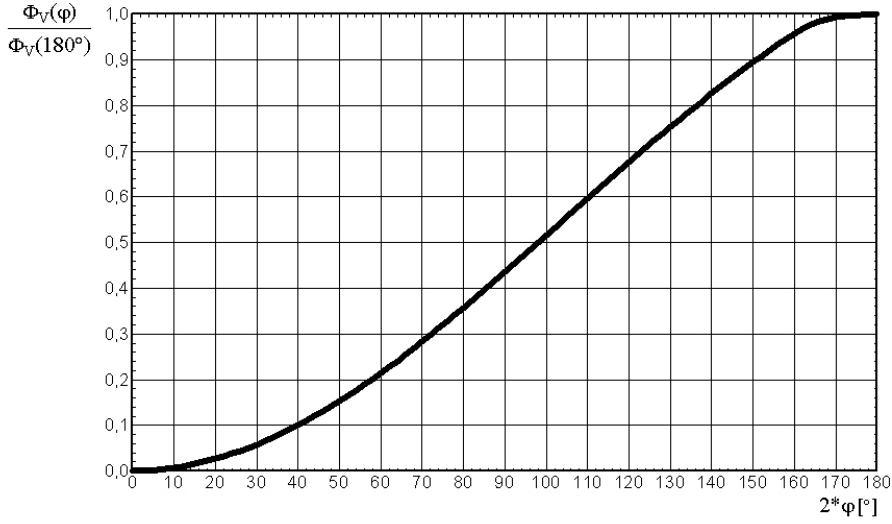
$I_{rel} = f(\varphi)$; $T_S = 25°C$



相对偏通量 第20页 2)

Relative Partial flux2) page 20

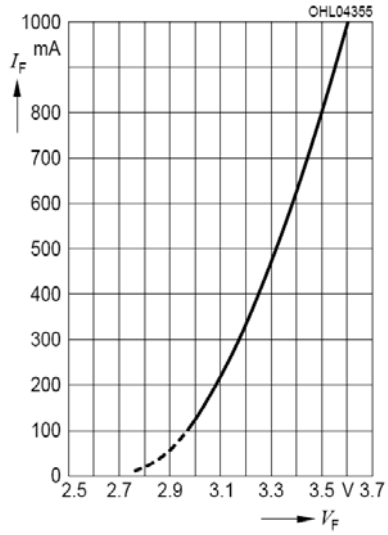
$\Phi_V/\Phi_V(90°) = f(\varphi)$; $T_S = 25°C$



正向电流/芯片 第20页 2)

Forward Current per chip2) page 20

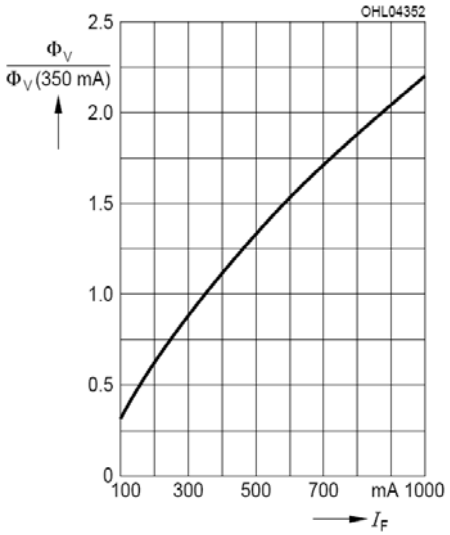
$I_F = f(V_F)$; $T_S = 25°C$



相对光通量 第20页 2)

Relative Luminous Flux2) page 20

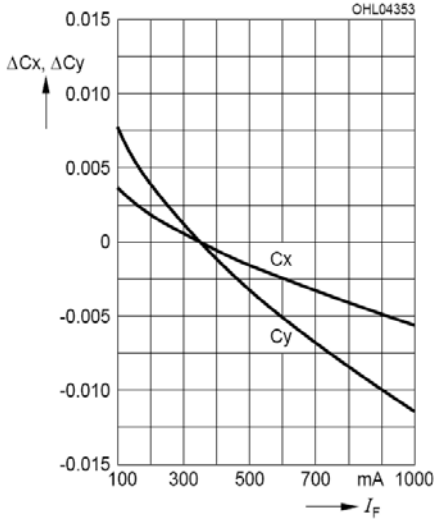
$\Phi_V/\Phi_V(350\ mA) = f(I_F)$; $T_S = 25°C$



色度坐标位移 第20页 2)

Chromaticity Coordinate Shift2) page 20

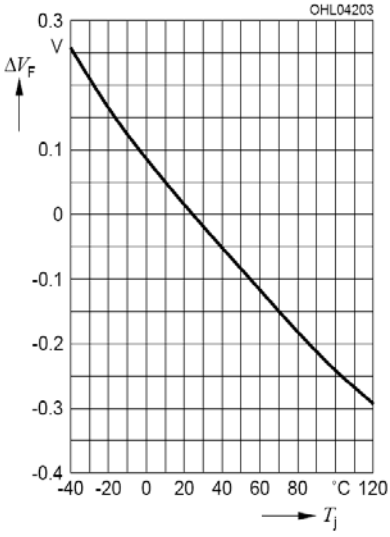
$\Delta Cx, \Delta Cy = f(I_F)$; $T_S = 25°C$



相对正向电压/芯片 第20页 2)

Relative Forward Voltage per chip2) page 20

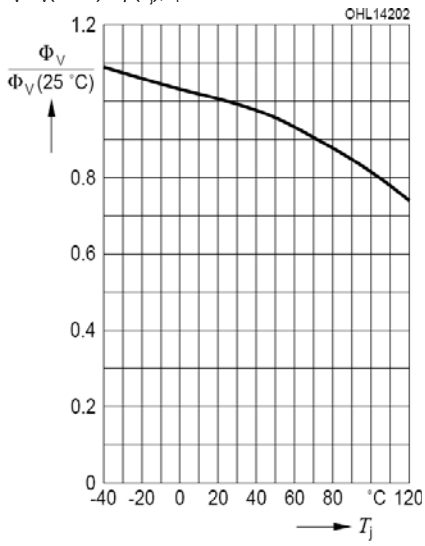
$\Delta V_F = V_F - V_F(25°C) = f(T_j)$; I_F= 350 mA



相对光通量 第20页 2)

Relative Luminous Flux2) page 20

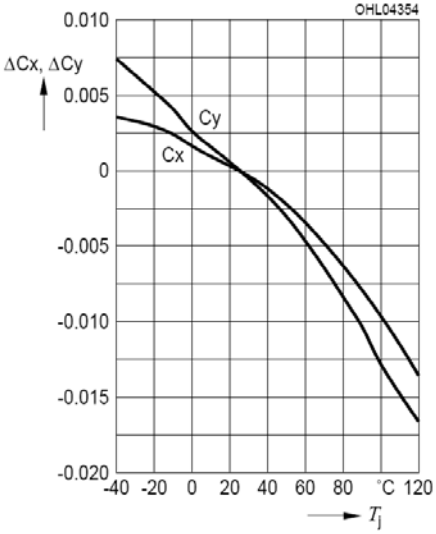
$\Phi_V/\Phi_V(25°C) = f(T_j)$; I_F = 350 mA



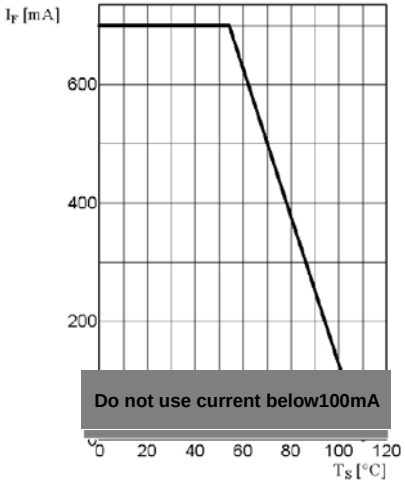
色度坐标位移 第20页 2)

Chromaticity Coordinate Shift2) page 20

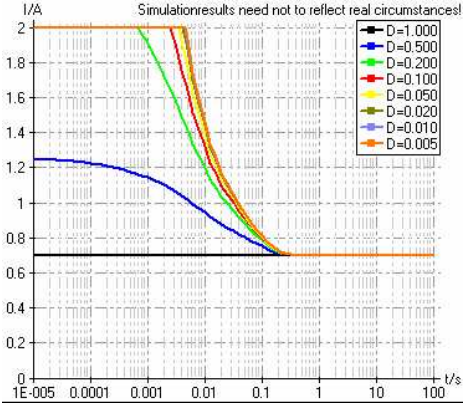
$\Delta Cx, \Delta Cy = f(T_j)$; I_F = 350 mA



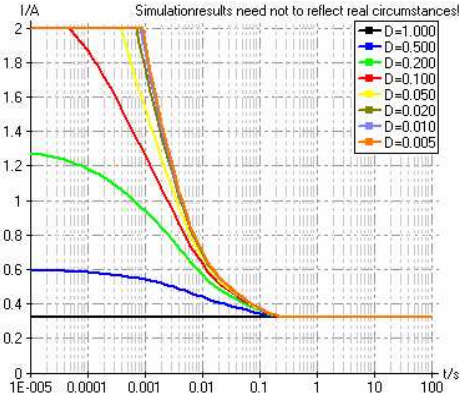
最大允许正向电流
Max. Permissible Forward Current
$I_F = f(T_S)$



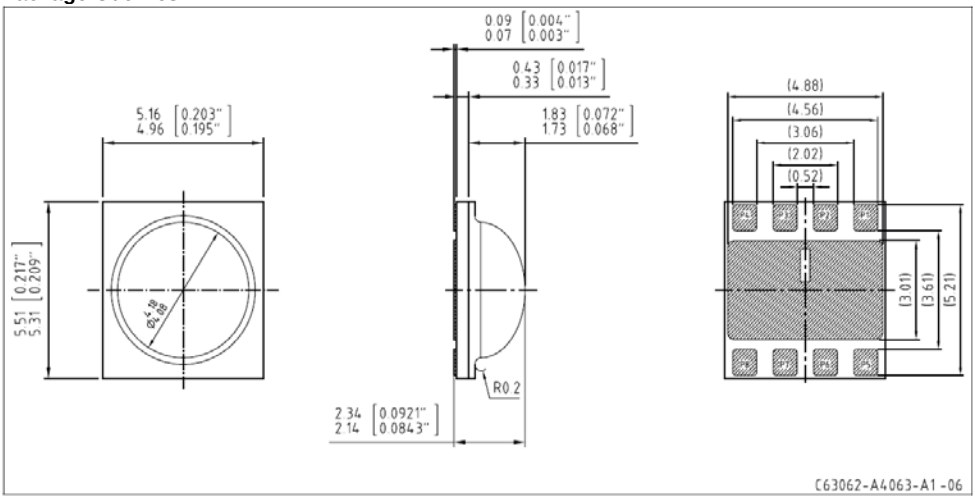
可允许脉冲调制能力 $I_F = f(t_p)$
Permissible Pulse Handling Capability
占空比 D = 参数，T_S = 25°C...45°C
Duty cycle D = parameter, T_S = 25°C...45°C



可允许脉冲调制能力 $I_F = f(t_p)$
Permissible Pulse Handling Capability
占空比 D = 参数，T_S = 85°C
Duty cycle D = parameter, T_S = 85°C



封装略图 第20页 6)
Package Outlines6) page 20



芯片位置 /Chip-Position：
1-4: 超白/ultra white

引脚分配/Pin-Assignment：

P1:	阳极；芯片 1 / Anode; Chip 1
P2:	阴极；芯片 1 / Cathode; Chip 1
P3:	阳极；芯片 2 / Anode; Chip 2
P4:	阴极；芯片 2 / Cathode; Chip 2
P5:	阴极；芯片 3 / Cathode; Chip 3
P6:	阳极；芯片 3 / Anode; Chip 3
P7:	阴极；芯片 4 / Cathode; Chip 4
P8:	阳极；芯片 4 / Anode; Chip 4

参考重量 / Approx. weight： 82 mg

腐蚀性优于 EN 60068-2-60（方法 4）：
经强化腐蚀试验：40°C / 90%rh / 15ppm H2S / 336h

Corrosion robustness better than EN 60068-2-60 (method 4):
with enhanced corrosion test: 40°C / 90%rh / 15ppm H2S / 336h

耐潮湿性 / Humidity Robustness

测试 / Test	*条件 / Conditions*	*时长 / Duration*	*失效标准 / Failure criteria*
潮湿高温工作寿命测试 (WHTOL) Wet High Temperature Operating Life Test (WHTOL)	85°C/85%RH, I_F = 50mA	500 小时（循环） 500h (cycled)	-ΔPhiV > 30% -灾难性故障 catastrophic failure

注释： 在室外应用中可能会出现高湿环境，制造商不对高湿环境中的应用负责。

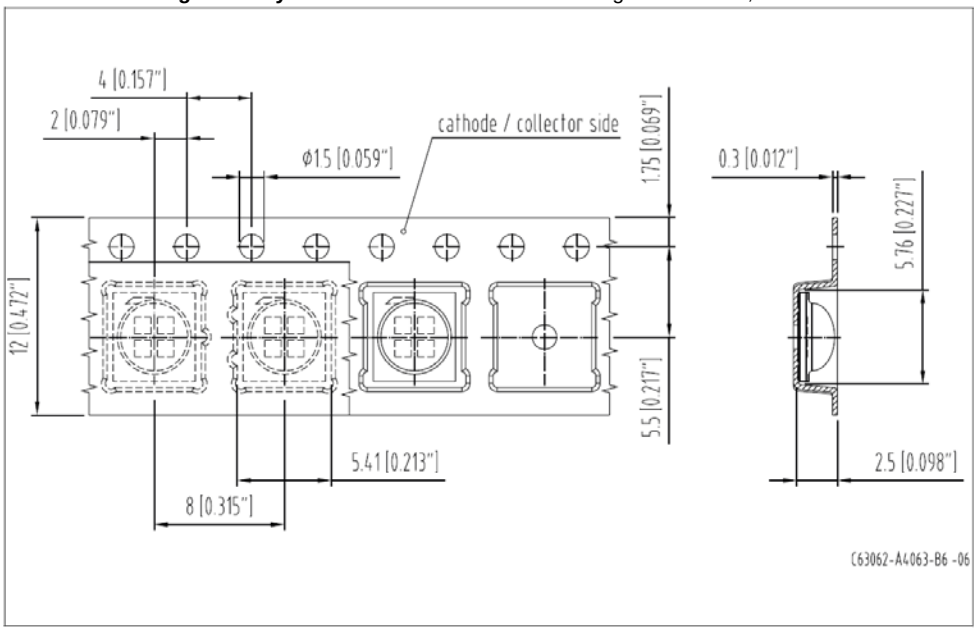
Note: Manufacturer disclaims all liability for applications in high humidity levels as it may appear in outdoor applications

封装方式/极性和方向 [第20页 6)]

Method of Packing / Polarity and Orientation[6) page 20]

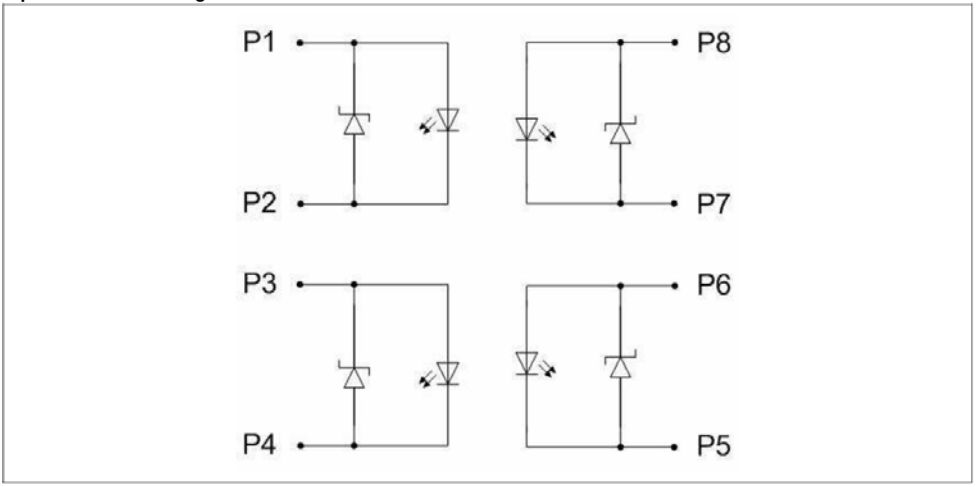
包装单元 200/卷，ø180 mm

Packing unit 200/reel, ø180 mm



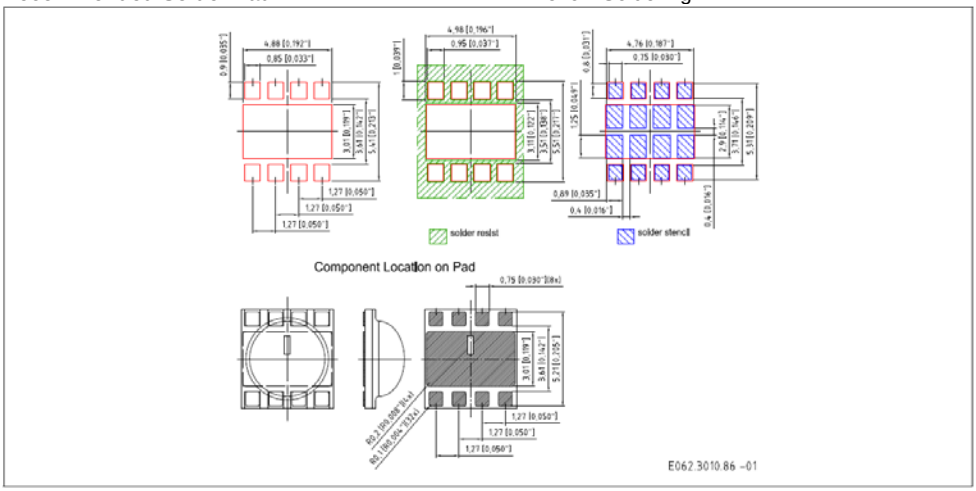
等效电路图

Equivalent Circuit Diagram



推荐焊盘
Recommended Solder Pad

回流焊接 第20页 6)
Reflow Soldering 6) page 20



焊接条件
Soldering Conditions

预处理依照 JEDEC 2 级标准
Preconditioning acc. to JEDEC Level 2

注释：该封装不适合进行湿洗。

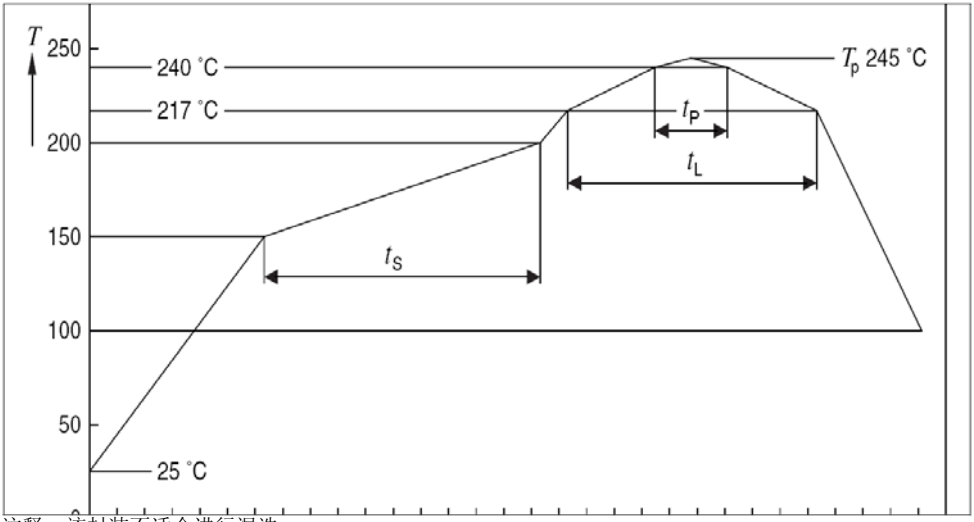
Note: Package not suitable for wetcleaning.

焊接条件
Soldering Conditions

预处理依照 JEDEC 4 级标准
Preconditioning acc. to JEDEC Level 4

无铅焊接的回流焊接温度曲线简图
Reflow Soldering Profile for lead free soldering

（依照 J-STD-020D.1 标准）
(acc. to J-STD-020D.1)

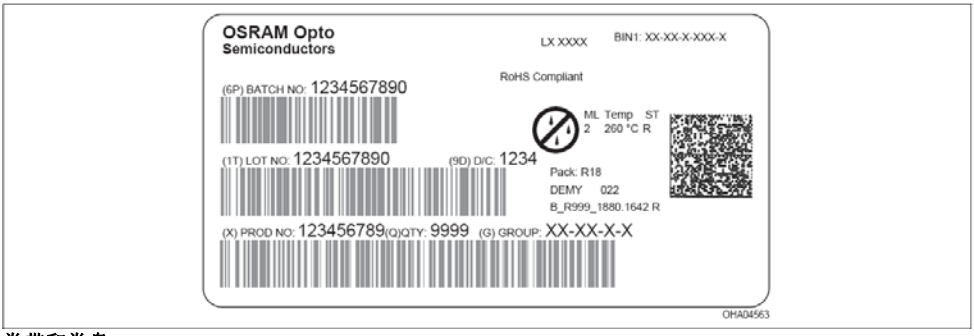


注释：该封装不适合进行湿洗。

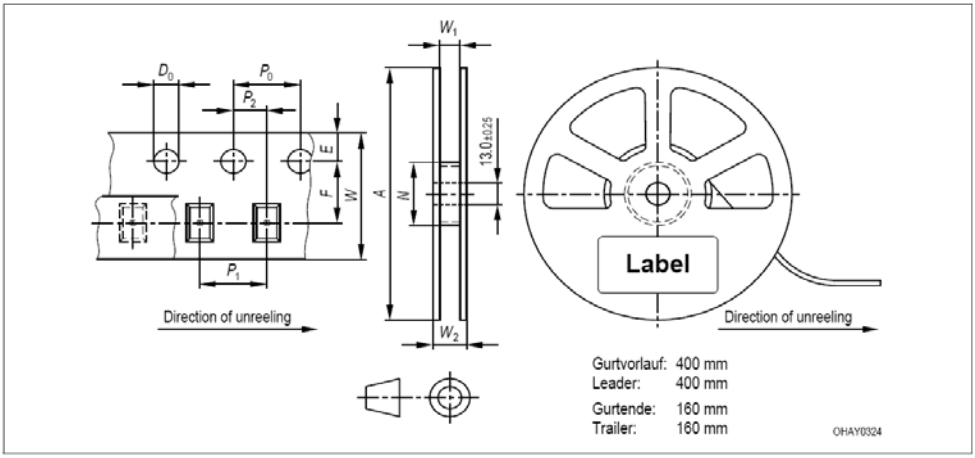
Note: Package not suitable for wetcleaning.

曲线轮廓特征 / Profile Feature	无铅（锡银铜）组件 / Pb-Free (SnAgCu) Assembly	
	推荐值 / Recommendation	大额定值 / Max. Ratings
预热前的升温速度*) / Ramp-up Rate to Peak*) 从 25°C 升至 150°C / 25°C to 150°C	2°C/秒 / 2°C / sec	3°C/秒 / 3°C / sec
从 $T_{S最小值}$ 升至 $T_{S最大值}$ 的时间 t_s Time t_s from T_{Smin} to T_{Smax} （从 150°C 升至 200°C / 150°C to 200°C）	100 秒/100 s	最小值 60 秒，最大值 120 秒 min. 60 sec max. 120 sec
到达峰值前的升温速度*) Ramp-up Rate to Peak*) 从 T_{Smax} 升至 T_P / T_{Smax} to T_P	2°C/秒 / 2°C / sec	3°C/秒 / 3°C/sec
液相线温度 T_L / Liquidus Temperture T_L	217°C	
温度高于 T_L 的时间 t_L / Time t_L above T_L	80 秒 / 80 sec	最大值 100 秒 / max. 100 sec
峰值温度 T_P / Peak Temperature T_P	245°C	最大值 260°C / max. 260°C
温度保持在指定峰值温度 T_P - 5K 的 5°C 范围内的时间 t_P / Time t_P within 5°C of the specified peak temperature T_P - 5K	20 秒 / 20 sec	最小值 10 秒，最大值 30 秒 min. 10 sec max.30 sec
降温速度 / Ramp-down Rate* 从 T_P 降至 100°C / T_P to 100°C	3°K/秒 / 3°K / sec	最大值 6°K/秒 6°K/sec maximum
从 25°C 升至峰值温度的时间 Time 25°C to Peak temperature		最大值 8 分钟 max. 8 min.

条形码——产品标签 (BPL)
Barcode-Product-Label (BPL)



卷带和卷盘
Tape and Reel



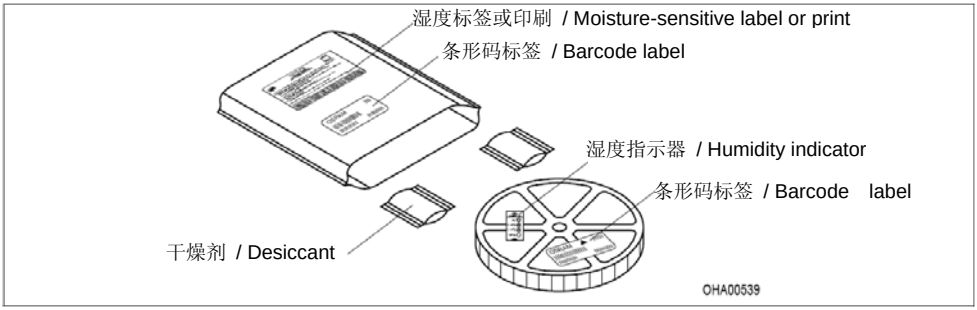
卷带尺寸（单位：mm（英寸））/ Tape dimensions in mm (inch)

W	P_0	P_1	P_2	D_0	E	F
$12^{+0.3}_{-0.1}$	4 ± 0.1 (0.157 ± 0.004)	8 ± 0.1 (0.315 ± 0.004)	2 ± 0.05 (0.079 ± 0.002)	1.5 + 0.1 (0.059 + 0.004)	1.75 ± 0.1 (0.069 ± 0.004)	5.5 ± 0.05 (0.217 ± 0.002)

卷盘尺寸（单位：mm（英寸））/Reel dimensions in mm (inch)

A	W	$N_{最小值}$ / N_{min}	W_1	$W_{2\ 最大值}$ / $W_{2\ max}$
180 (7)	12 (0.472)	60 (2.362)	12.4 + 2 (0.488 + 0.079)	18.4 (0.724)

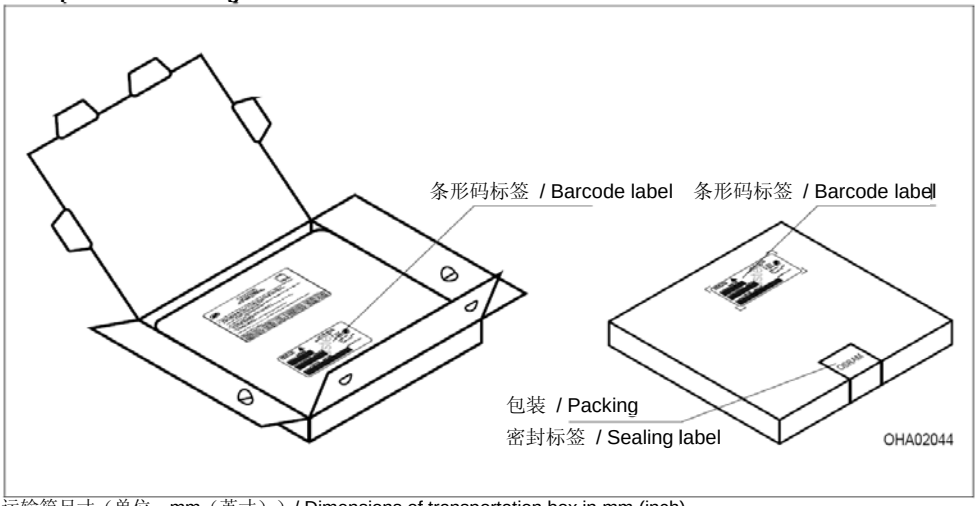
干式充填工艺和材料
Dry Packing Process and Materials



注释： 湿敏产品包装在装有干燥剂和湿度卡的干燥袋子中。
关于干式充填的详细信息，请参阅网站资料和简明版产品目录中“干式充填”标题下的“卷带和卷盘”章节。
您还可以找到 JEDEC 等规范性参考。

Note: Moisture-sensitive product is packed in a dry bag containing desiccant and a humidity card.
Regarding dry pack you will find further information in the internet and in the Short Form Catalog in chapter “Tape and Reel” under the topic “Dry Pack”. Here you will also find the normative references like JEDEC.

运输包装和材料
Transportation Packing and Materials .



运输箱尺寸（单位：mm（英寸））/ Dimensions of transportation box in mm (inch)

宽度 / Width	*长度 / Length*	*高度 / Height*
200 ±5 (7,874 ±0,1968±)	200 ±5 (7,874 ±0,1968)	30 ±5 (1,1811 ±0,1968)

修订记录 / Revision History：2011-06-30
先前版本 / Previous Version： 2010-12-13

页码 Page	更改内容（自上次修订后的主要更改） Subjects (major changes since last revision)	修改日期 Date of change
全部 / all	创建最终规格书 /Final datasheet created	2010-10-25
2	纠正色温 / correction of colortemperature	2010-11-17
13	纠正耐潮湿性 / humidity robustness corrected	2010-12-08
13	纠正引脚分配/状态“初步规格书” correction of PIN-Assignment / status „preliminary Datasheet“	2010-12-13
14	纠正等效电路图 / correction of equivalent circuit diagramm	2011-06-30

注释： 由于 IEC 608251（第二版 2007-03）标准取消了 LED 部分，所以本产品根据 IEC/CIE 双重标准 CIE S009/E:2002（“灯和灯系统的光生物安全性”）- IEC 62471（第一版 2006-07）进行眼睛安全评估。在该 CIE 标准的风险分组系统中，本数据表中指定的 LED 属于“中等风险”组（与接触时间为 0.25 秒的可见光谱范围内的装置相关）。在实际环境（包括接触时间、瞳孔、观察距离）中，认为这些装置对人眼没有危害。但是，作为原则问题，必须提及强烈光源具有致盲效应，因此很可能发生二次曝光。直视其他明亮光源（如车前灯）时也是如此，视敏度可能会暂时下降，也可能会出现余像，从而导致困扰、烦恼、视障甚至意外事故，具体取决于当时的情况。

Note: Due to the cancellation of the LED from IEC 608251 (2nd edition 2007-03), the evaluation of eye safety occurs according to the dual IEC/CIE logo standard CIE S009/E:2002 ("photobiological safety of lamps and lamp systems")- IEC 62471 (1st edition 2006-07). Within the risk grouping system of this CIE standard, the LEDs specified in this data sheet fall into the "moderate risk" group (relating to devices in the visible spectrum with an exposure time of 0.25s). Under real circumstances (for exposure time, eye pupils, observation distance), it is assumed that no endangerment to the eye exists from these devices. As a matter of principle, however, it should be mentioned that intense light sources have a high secondary exposure potential due to their blinding effect. As is also true when viewing other bright light sources (e.g. headlights), temporary reduction in visual acuity and afterimages can occur, leading to irritation, annoyance, visual impairment, and even accidents, depending on the situation.

请注意！

元件类型的描述性信息不应被视作对特许的保证。
欧司朗保留交货条件和变更设计的权力。因技术需要，元件可能包含危险物质。如果对相关信息有疑问，请联系我们的销售部门。
如需打印或下载，请到公司网站寻找最新的版本。

包装

请联系您所熟悉的物资回收公司。我们也可以帮助您联系最近的销售办事处。如果您已对包装材料进行分类，我们将根据协议进行回收，所产生的运输费用须由您承担。对于未经分类即退回本公司或我们没有责任接受的包装材料，我们将开具发票由您支付因此产生的一切费用。

生命支持装置或系统所采用的元件必须获取用于该目的的明确授权！仅当获得欧司朗光电半导体的明确书面许可时，方可将关键元件 第20页 7) 用于生命支持装置或系统 第20页 8)。

Attention please!

The information describes the type of component and shall not be considered as assured characteristics.
Terms of delivery and rights to change design reserved. Due to technical requirements components may contain dangerous substances. For information on the types in question please contact our Sales Organization.
If printed or downloaded, please find the latest version in the Internet.

Packing

Please use the recycling operators known to you. We can also help you – get in touch with your nearest sales office. By agreement we will take packing material back, if it is sorted. You must bear the costs of transport. For packing material that is returned to us unsorted or which we are not obliged to accept, we shall have to invoice you for any costs incurred.

Components used in life-support devices or systems must be expressly authorized for such purpose! Critical components[7) page 20] may only be used in life-support devices or systems[8) page 20] with the express written approval of OSRAM OS.

备注：

1) 亮度值的测量是当电流脉冲为 25 ms（典型值）时进行的，内部重现性为 +/-8%，扩展不确定度为 +/-11%（依据 GUM，膨胀系数 k = 3）。

2) 由于 LED 制造工艺的条件特殊，典型或计算得出的技术参数数据仅能反映统计数据，而不等同于各产品的实际参数，它们可能与典型或计算得出的典型特征线数据不同。如果需要（如由于技术改进），这些典型数据将有所变更，恕不另行通知。

3) 色度坐标的测量是当电流脉冲为 25 ms（典型值）时进行的，内部重现性为 +/-0.005，可扩展不确定度为 +/-0.01（依据 GUM，膨胀系数 k = 3）。

4) 正向电压的测量是当电流脉冲为 8 ms（典型值）时进行的，内部重现性为 +/-0.05 V，可扩展不确定度为 +/-0.1 V（依据 GUM，膨胀系数 k = 3）。

5) 在虚线范围内，单个包装单元内的不同 LED 之间的明暗差别会更大。

6) 尺寸单位指定为：mm（英寸）

7) 关键元件指用在生命支持装置或系统中、一旦发生故障即会引起装置或系统故障或影响其安全性或有效性的元件。

8) 生命支持装置或系统拟用于 (a) 植入人体或 (b) 支持和/或维持人的生命。
如果发生故障，即会威胁使用者的健康和生命。

Remarks:

1) Brightness values are measured during a current pulse of typical 25 ms, with an internal reproducibility of +/-8% and an expanded uncertainty of +/-11% (acc. to GUM with a coverage factor of k = 3).

2) Due to the special conditions of the manufacturing processes of LED, the typical data or calculated correlations of technical parameters can only reflect statistical figures. These do not necessarily correspond to the actual parameters of each single product, which could differ from the typical data and calculated correlations or the typical characeristic line.
If requested, e.g. because of technical improvements, these typ. data will be changed without any further notice.

3) Chromaticity coordinates are measured during a current pulse of typical 25 ms, with an internal reproducibility of +/-0,005 and an expanded uncertainty of +/-0,01 (acc. to GUM with a coverage factor of k = 3).

4) The forward voltage is measured during a current pulse of typical 8 ms, with an internal reproducibility of +/- 0,05 V and an expanded uncertainty of +/- 0,1 V (acc. to GUM with a coverage factor of k=3).

5) In the range where the line of the graph is broken, you must expect higher brightness differences between single LEDs within one packing unit.

6) Dimensions are specified as follows: mm (inch).

7) A critical component is a component used in a life-support device or system whose failure can reasonably be expected to cause the failure of that life-support device or system, or to affect its safety or the effectiveness of that device or system.

8) Life support devices or systems are intended
(a) to be implanted in the human body,
or
(b) to support and/or maintain and sustain human life. If they fail, it is reasonable to assume that the health and the life of the user may be endangered.

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