

ETKİN TIBBİ CİHAZLAR SANAYİ VE TİCARET A.Ş.  
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Considering the law numbered 4703 and related regulations for products and accessories that use LED lighting technology, which are produced to be used in surgical interventions and diagnostic medical applications, and whose relevant regulations, product descriptions and applied standards are specified below.

*The following "X" may contain the letters "A-Z" and/or "0-9" and/or "Space" and/or "+/-". All products and accessories produced according to this nomenclature; According to the T.C. Ministry of Health 2017/745 Medical Device Regulation, we are Class I-other Active Device and declared that this EU DECLARATION OF CONFORMITY is prepared in accordance with Annex IV.*

GMDN: 37332

GTIP : 9018.90.84.00.19

**ETKİN TIBBİ CİHAZLAR BRAND LIGHTS**

| DESCRIPTION                   | CODE                                                      | BASIC UDI-DI    |
|-------------------------------|-----------------------------------------------------------|-----------------|
| Surgical Light                | ETC LED ELITE X<br>XXXXXXXXXX/XXXXXXXXXX/XXXXXXXXXX-XX    | 86800814702035U |
| Surgical Light                | ETC LED MASTER X<br>XXXXXXXXXX/XXXXXXXXXX/XXXXXXXXXX-XX   | 86800814702035U |
| Surgical Light                | ETC LED PERGAMON X<br>XXXXXXXXXX/XXXXXXXXXX/XXXXXXXXXX-XX | 86800814702035U |
| Surgical Light                | ETC LED SMYRNA X<br>XXXXXXXXXX/XXXXXXXXXX/XXXXXXXXXX-XX   | 86800814702035U |
| Minor Surgical Light          | ETC LED ANKA X<br>XXXXXXXXXX/XXXXXXXXXX/XXXXXXXXXX-XX     | 86800814714036D |
| Examination (Diagnosis) Light | ETC LED KAYRA X XXXXXXXXXXXX-XX                           | 86800814724146R |

**STANDARTS**

TS EN 60601-1:2009

TS 3033 EN 60529:1997; TS 3033 EN 60529/T1:1997; TS 3033 EN 60529/T2:2004; TS 3033 EN 60529/A1:2005/A2:2014

TS EN 60601-1-2:2016; EN 60601-1-2:2015; IEC 60601-1-2:2014

TS EN 60601-2-41:2011



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31.08.2021 / İzmir