

# LED SpA

## PROGETTAZIONI E PRODUZIONI ELETTRONICHE



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TO WHOM IT MAY CONCERN

Our Ref. : **Declaration of Conformity Electrosurgical Accessories**

We

Name of manufacture: **LED SpA**

Country of origin: **ITALY**

Address/Tel/Fax: Via M.T. Cicerone 138 I-03100 FROSINONE / +39 0692870045 / +39 0692870046

Facility/ies (address): Via Selciatella 40 I-04011 APRILIA (LT) – ITALY (EUROPE)

**Declare under our sole responsibility that quality of**

Product Name	GMDN										
PENCIL	44677	REF	00201.01	00201.02	00206.00	00206.40					
		EAN13	8033638322222	8033638323779	8033638321232	8033638324554					
PENCIL S	42552 44680	REF	00205.00	00205.40							
		EAN13	8033638321225	8033638324561							
CONNECTION	44683	REF	00402.00	00402.01	00402.02	00402.03	00402.04	00404.02	00404.04	00404.08	00404.09
		EAN13	8033638321270	8033638323762	8033638323786	8033638324592	8033638324608	8033638322680	8033638321263	8033638324547	8033638324714
		REF	00411.00	00412.00	00413.00	00414.00	00415.00	00416.00	00417.00	00418.00	
		EAN13	8033638321249	8033638321256	8033638323793	8033638324615	8033638324622	8033638324639	8033638324646	8033638324530	
NEUTRAL	11500	REF	00400.00	00401.00	00401.01	00401.02	00401.03	00401.10	00401.11	00401.12	00401.20
		EAN13	803363832	8033638322949	8033638322956	8033638321430	8033638321447	8033638324653	8033638324677	8033638324707	8033638324660
		REF	00401.21	00401.22	00403.01	00403.02	5365A	6429A			
		EAN13	8033638324684	8033638324691	8033638322246	8033638323212	8033638322253	8033638322703			
ELECTRODE	44683	REF	00500.00	00500.00/L	00500.03	00500.D1	00500.D12	00500.D1/S	00500.D12/S	00500.L1	00500.L1/L
		EAN13	8033638322277	8033638322215	8033638324257	8033638324226	8033638324233	8033638320000	8033638320000	8033638322284	8033638322116
		REF	00500.L2	00500.L2/L	00500.L3	00500.L3/L	00500.L4	00500.L4/L	00500.L5	00500.L5/L	00500.L6
		EAN13	8033638322291	8033638322123	8033638322307	033638322130	8033638322314	8033638322147	8033638322321	8033638322154	8033638322338
		REF	00500.L6/L	00500.L7	00500.L7/L	00500.L8	00500.L8/L	00500.L9	00500.L9/L	00500.L10	00500.L10/L
		EAN13	8033638322161	8033638322345	8033638322178	8033638322352	8033638322185	8033638322369	8033638322208	8033638322376	8033638322192
		REF	00500.S05	00500.S10	00500.S15	500500.D1/S	500500.D12/S	500500.L1	500500.L1/L	500500.L2	500500.L2/L
		EAN13	8033638324264	8033638324271	8033638324288	8033638320000	8033638324400	8033638322475	8033638322574	8033638322482	8033638322581
		REF	500500.L3	500500.L3/L	500500.L4	500500.L4/L	500500.L5	500500.L5/L	500500.L6	500500.L6/L	500500.L7
		EAN13	8033638322499	8033638322598	8033638322505	8033638322604	8033638322512	8033638322611	8033638322529	8033638322628	8033638322536
		REF	500500.L7/L	500500.L8	500500.L8/L	500500.L9	500500.L9/L	500500.L10	500500.L10/L	152-110	152-112
		EAN13	8033638322635	8033638322543	8033638322642	8033638322550	8033638322659	8033638322567	8033638322666	8033638323373	8033638323380
		REF	152-115	152-120	152-122	152-125	152-130	152-132	152-140	152-142	152-145
		EAN13	8033638323403	8033638323410	8033638323427	8033638323434	8033638323441	8033638323458	8033638323465	8033638323472	8033638323489
		REF	152-150	152-152	152-160	152-162	152-165	152-175-10	152-190-13	152-190-20	152-195
EAN13	8033638323496	8033638323502	8033638323519	8033638323526	8033638323533	8033638323540	8033638323557	8033638323564	8033638323571		
BIPOLAR	44683	REF	110-700	110-750NS	110-755NS	110-760NS	310-110-05	310-112-05	310-140-10	310-140-20	310-142-10
		EAN13	8033638323397	8033638323717	8033638323724	8033638323731	8033638323588	8033638323595	8033638323601	8033638323618	8033638323625
		REF	310-142-20	310-180-10	310-180-20	310-182-10	310-185-10	310-510	310-550	310-590	410-100-15
		EAN13	8033638323632	8033638323649	8033638323656	8033638323663	8033638323670	8033638323687	8033638323694	8033638323700	8033638324486
MONOPOLAR	44683	REF	330-134-20	330-160							
		EAN13	8033638323755	8033638323748							

Classification:

EU Classification (Rule:9)	I	
	I*	
	IIa	
	IIb	X
	III	

**Complies with all relevant requirements of:**

■ Directive 93/42/EEC

(Annex: II)

Notified Body: 0051 (IMQ-Italy)

EC Certificate: 116/MDD

Applied standard(s):

Standard No	Title	Description
ISO 9001:15	Quality Management Systems	Quality System
EN ISO 13485:16	Quality Management Systems	Medical Device Quality System
EN 60601-1	MEDICAL ELECTRICAL EQUIPMENT – GENERAL STD.	General Requirement for Safety
EN 60601-2-2	MEDICAL ELECTRICAL EQUIPMENT – PARTICULAR STD.	Particular Requirement for the Safety of High Frequency Surgical Equipment

Valid until: 12/04/2022

Date/Signature/position/Stamp manufacture: 15/03/2019

LED SpA  
P.IVA / C.F. 00704680602

Quality Assurance Mgr.