

PRODUCT CERTIFICATION
KIWA CERMET

Directive 93/42/EEC

 **MEDENCY**
TECHNOLOGY | INNOVATION | PASSION

CE Conformity Statement

For the devices named as follows

PRIMO TRIPLO

CODE: LAMED009.3 | Max Power: 10W | Wavelength 450/635/980nm

manufactured by

Medency S.r.l.

Based in Piazza della Libertà 49

36077 Altavilla (Vicenza) Italy

pursuant to Annex II of Directive 93/42 / EEC, excluding point 4, implemented by Legislative Decree 46/97 and its integration with Directive 2007/47 / EC implemented by Legislative Decree 37 of 01/25/2010 and with the application of Directive 99/05 / EC, declares under its own exclusive and complete responsibility that:

- the device complies the essential safety requirements set out in Annex I of Directive 93/42 / EEC and its integration with Directive 2007/47 / EC; the design, construction and final checks are carried out as indicated by the Complete Quality Assurance System Reg. No: 31374 del 31/10/17 issued by the notified body **Kiwa Cermet Italia S.p.a n.0476**. Via Cadriano 23, 40057 - Granarolo dell'Emilia (BO) www.kiwacermet.it issued on 31/10/17
- the device is classified as **Class II B**.
- the relevant technical documentation, specified in Annex II point 6.1, of Directive 93/42 / EEC is kept at the disposal of the competent authority for a period of ten years from the last date of product manufacturing.

Directive and standards	
93/42/CE and subsequent amendments	EN 60601-2-22:2013
RoHS – 2011/65/UE	EN 62304/A1:2015
RAEE – 2012/19/UE	CEI EN 62133:2 2017
CEI EN 60825-1:2015	UNI CEI EN ISO 14971:2012
IEC 60601-1:2015/A1:2012	UNI EN ISO 10993-1:2010
IEC 60601-1-2:2014	UNI EN ISO 9001:2015
EN 60601-1-6:2010	UNI EN ISO 13485:2016
Directive 2014/53/UE RED Radio Equipment Directive (ETSI standard EN 300 328, EN 301 489-17, 301 489-1)	

Place and date of issue: Altavilla – Vicenza (Italy) / /2022

*Variable according to product type and variant


0476

Stamp and signature of Company Director :

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