

**TELEFAX****SEMRAU**  
KURT SEMRAU GMBH

Glühlampen für Medizin und Technik

Absender / Sender : Kurt Semrau GmbH, Schützenstraße 26A, 78532 Tuttlingen  
Kurt Semrau GmbH, Postfach 47 27, 78512 Tuttlingen

Empfänger / Receiver : GIMA S.p.A.

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**CE-MARKING OF LIGHT BULBS MADE BY SEMRAU**

Dear Mrs. Teresa Sesti,

further to your inquiry of September 16, 2010 regarding the light bulbs delivered by the company Kurt Semrau GmbH, we can make the following statement:

The Semrau light bulbs are **no** products to which Directive 93/42/EEC on Medical Devices applies, but they are wear or spare parts.

Accordingly, this product **cannot** or **must not** be affixed with a CE-marking. If the definition of accessory applied, a not insignificant number of other components e.g. halogen lamps, power cords, mains switches, fuses etc. as are used in medical devices would have to bear a CE-marking according to the Law on Medical Devices (MPG) or the Directive 93/42/EEC.

This was also confirmed to us by Dekra Certification Services GmbH.

The Low Voltage Directive 73/23/EEC cannot be applied to these light bulbs either as it only applies to operating means operated or connected at a nominal voltage between 50 and 1000 V for alternating current and between 75 and 1500 V for direct current.

We hope this information has contributed to clarifying the situation and trust that you will share our opinion.

Best regards  
KURT SEMRAU GmbH

ppa. P.Goll

