

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

