



## TOP MANAGEMENT ADVISORS Ltd.

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### **KROS-M, a leading manufacturer of condoms and sex lubricants, certified to ISO 9001:2008 and ISO 13485:2003**

A Bulgarian company present on worldwide markets with its top quality products, **KROS-M**, achieved certification to ISO 9001:2008 and ISO 13485:2003 (for medical devices) for its sex lubricants manufacturing facilities.

The Quality Management System has been developed under the guidance of consultants from **Top Management Advisors** supported by field experts from **Revolt-64**.

The certification body has been **Lloyd's Register Quality Assurance** which operates in Bulgaria according to its highest international standards.

**KROS-M Ltd.** was established in 1996 as a condom manufacturer but it has gradually broadened its product range. The most popular brands of the company, Sportex, Fresh and Torpido, are sold in Bulgaria and in tens of countries worldwide.

The scope of the new Quality Management System covers the design, manufacture and sales of sex lubricants which are subject to regulatory controls as medical devices.



**Manufacturing medical devices for healthy people is a special challenge** reflected in the exclusive care for the quality of the products which must guarantee the health and the satisfaction of the final consumers.

**KROS-M Ltd.** is the most recent customer of the consulting company **Top Management Advisors (TMA)** in the health care sector. TMA has been providing assistance for more than 15 years in raising the efficiency of health care businesses and supporting them in becoming compliant with general management standards such as ISO 9001 and specific international standards such as ISO 13485 for medical devices. In the pharmaceutical sector, specific assistance has been offered to achieve compliance with the national regulations and European Union guidance on Good Distribution Practices.

Specific information on standards applicable to the health care industries can be obtained by the consultants of Top Management Advisors Ltd.