



ARAZY GROUP
Medical Device Consultants
Fact Sheet N° 1
July 2006



**SERVICES PROVIDED BY YOUR PROFESSIONAL
REGULATORY AUTHORIZED REPRESENTATIVE**

Introduction

As your Authorized Representative in Europe, **Medes Ltd. UK** shall handle your registration as foreign manufacturer of medical devices in the EU and listing your products before the Health Authority of a Member State. Once this has been done, all your medical products will obtain CE mark and **Medes Ltd. UK** will take care of its maintenance, either answering for you in cases of customer complaints, adverse events, incident, and also in recall reporting of CE marked products to the Regulatory Authorities in EU. In addition, **Medes Ltd. UK** will provide consulting services for writing or reviewing as well as maintaining Technical Files.

Customer Complaints/Incidents

In case of Customer Complaint / Incidents would be arisen, your Authorized Representative in Europe, **Medes Ltd. UK** will resort to standardized surveillance procedures compliant with the requirements issued by European Authorities. Before any action is taken, your Company will be notified in 48 hours by **Medes Ltd. UK** in the event of any query or requirement of the Competent Authority or any other interested party in relation with the marketed products. This includes customer complaints, incidents and near incidents, post-marketing feedback and marketing issues. Information of a customer contact to **Medes Ltd. UK** on occasion of a

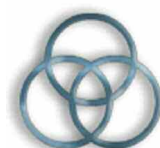
Customer Complaint or post-marketing feedback will be sent to your Company. In all these cases, a detailed description will be provided as well as the necessary advice on how to proceed thereon. A similar action will be adopted should your company feel that a certain incident should be reported to the authorities (according to the surveillance procedure provided by us). Any discussion on such incidents, decisions taken, and recommendation on how to proceed with these reports, will be via **Medes Ltd. UK** and Arazy Group expert consultants.

Medes Ltd. UK will provide the Surveillance and Customer Complaint / Incidents procedures to be implemented in your Company. These procedures will enable you to act the event of Customer Complaint and the need to report to the authorities the adverse effects of those incidents that call for a report. Implementation of these procedures is a statutory requirement.

Labeling

Medes Ltd. UK will provide your Company accurate labeling instructions as required as part of CE marking. We specially emphasize that your Company is legally asked to include information on the Authorized Representative (name, address and contact information) in the label, external packaging, and instructions manual of each product unit or batch.

Medes Ltd. UK is a member of Arazy Group



ARAZY GROUP
MEDICAL DEVICE CONSULTANTS

Mizpe Aviv, Industrial Park 13 - M.P. Misgav 20187 - Israel
Phone: +972 4994 7880 - Fax: +972 4994 4224
beinfo@arazygroup.com - www.arazygroup.com